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2	FEDERAL TRADE COMMISSION OFFICE OF ADMINISTRATIVE LAW JUDGES						
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4	In the Matter of: )						
5	IMPAX LABORATORIES, INC, )						
6	a corporation, ) Docket No. 9373						
7	Respondent. )						
8	)						
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12	TUESDAY, OCTOBER 31, 2017						
13	9:45 a.m.						
14	TRIAL VOLUME 5						
15	PUBLIC RECORD						
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17	BEFORE THE HONORABLE D. MICHAEL CHAPPELL						
18	Chief Administrative Law Judge						
19	Federal Trade Commission						
20	600 Pennsylvania Avenue, N.W.						
21	Washington, D.C.						
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25	Reported by: Susanne Bergling, RMR-CRR-CLR						

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- 1 PROCEEDINGS
- 2 - -
- JUDGE CHAPPELL: Okay, let's go back on the
- 4 record.
- 5 First of all, I noticed that I -- based on some
- 6 email traffic, there were two motions to compel. Were
- 7 those filed?
- 8 MR. LOUGHLIN: I believe they were filed, Your
- 9 Honor, but we withdrew them.
- 10 JUDGE CHAPPELL: Both of them? Because the
- 11 followup email referred to one name but not Bingol.
- MR. LOUGHLIN: We withdrew both.
- 13 JUDGE CHAPPELL: Okay. I'll need you to --
- 14 whoever filed them needs to file a notice of withdrawal,
- 15 not a motion to withdraw, a notice of withdrawal,
- 16 because motions to compel have their own set of
- 17 deadlines and issues once they're in the system.
- 18 MR. LOUGHLIN: We will do that, Your Honor.
- 19 JUDGE CHAPPELL: And if you haven't done one in
- 20 this case, you can look in the past. It's something
- 21 that's commonly done, notice of withdrawal.
- 22 MR. LOUGHLIN: Okay. Thank you, Your Honor.
- 23 JUDGE CHAPPELL: I noticed late yesterday I got
- 24 a request to possibly go late today. I'm still looking
- 25 into that, on whether the support staff is available.

- 1 What I will do is trim lunch to 45 minutes today, if
- 2 possible go -- we will go no later than 6:15. Those two
- 3 things together would give you an extra hour of
- 4 testimony, if that works out.
- 5 MR. LOUGHLIN: Thank you, Your Honor.
- 6 JUDGE CHAPPELL: I think we can go until 6:00
- 7 either way if we need to.
- 8 MR. LOUGHLIN: Thank you, Your Honor.
- 9 JUDGE CHAPPELL: So schedule your witnesses
- 10 accordingly.
- 11 MR. LOUGHLIN: Thank you.
- 12 JUDGE CHAPPELL: Next witness.
- MR. HASSI: Your Honor, if I might, on
- 14 scheduling, I did have one other -- I wanted to let Your
- 15 Honor know where we are, having evaluated the case over
- 16 the weekend.
- 17 JUDGE CHAPPELL: All right.
- 18 MR. HASSI: So Complaint Counsel has indicated
- 19 that they expect to wrap up their case this Friday. We
- 20 believe that our case would probably take four trial --
- 21 roughly four trial days, and that's including time for
- 22 cross, and so we're scheduled to start on Monday, the
- 23 6th.
- JUDGE CHAPPELL: Right. We are going Monday
- 25 through Thursday of next week. There's a federal

- 1 holiday next Friday.
- 2 MR. HASSI: Yes, Your Honor. And I quess what
- 3 I'm indicating is we have two fact witnesses that aren't
- 4 available next week but would be the following week.
- 5 One of them had to travel to Taiwan and can't be back in
- 6 time.
- What we would ask is we think we probably have
- 8 Monday, Tuesday, Wednesday covered. We have offered to
- 9 Complaint Counsel -- they have a rebuttal witness,
- 10 Mr. Hoxie. They're willing to take him out of turn,
- 11 subject to his availability, either late Wednesday or on
- 12 Thursday. And then we would ask to reconvene on -- if
- 13 at all possible, on Tuesday, the 14th, for those two
- 14 final fact witnesses. That would be Mr. Nestor and
- 15 Mr. Hsu, the CEO. He's the one who's in Taiwan and is
- 16 unavailable.
- 17 JUDGE CHAPPELL: Complaint Counsel can also
- 18 offer their rebuttal expert, if they intend to do so,
- 19 out of turn. We don't need to wait until the end for
- 20 that.
- MR. LOUGHLIN: Yes, Your Honor.
- 22 JUDGE CHAPPELL: We have done that before and,
- 23 if need be, we can do that.
- 24 MR. LOUGHLIN: And we are happy to do that, Your
- 25 Honor.

- 1 JUDGE CHAPPELL: So you think we'll have
- 2 somebody all four days next week?
- 3 MR. HASSI: I think we will have somebody all
- 4 four days, depending on when the rebuttal witness goes
- 5 on, either -- he may go on as early as Wednesday --
- 6 THE COURT: All right.
- 7 MR. HASSI: -- and may carry over into Thursday.
- 8 It will depend on how long the crosses go. Then and we
- 9 have two fact witnesses, both of them we think we can
- 10 get done in a day, and for that reason -- and, frankly,
- 11 for reasons of Mr. Hsu's return -- he lives on the West
- 12 Coast, is traveling to Taiwan, and I want to give him
- 13 one day to adjust before he takes the stand if that's
- 14 possible; hence, my request for the 14th as opposed to
- 15 Monday, the 13th.
- 16 JUDGE CHAPPELL: One day to adjust for the
- 17 approximately 14-hour time difference?
- 18 MR. HASSI: Yes, Your Honor.
- 19 JUDGE CHAPPELL: And then knock three more off
- 20 of that?
- MR. HASSI: Yes, Your Honor.
- 22 JUDGE CHAPPELL: All right. So just let me know
- 23 how it shakes out during the week.
- MR. HASSI: Thank you, Your Honor.
- JUDGE CHAPPELL: All right, thank you.

- 1 Next witness.
- MR. LOUGHLIN: Your Honor, Complaint Counsel
- 3 called Joseph Camargo, and my colleague Lauren Peay will
- 4 conduct the examination.
- 5 Whereupon--
- JOSEPH A. CAMARGO
- 7 a witness, called for examination, having been first
- 8 duly sworn, was examined and testified as follows:
- 9 MS. PEAY: Good morning, Your Honor. May it
- 10 please the Court. I am Lauren Peay on behalf of
- 11 Complaint Counsel.
- 12 DIRECT EXAMINATION
- 13 BY MS. PEAY:
- Q. Good morning, Mr. Camargo.
- 15 A. Good morning.
- 16 Q. Mr. Camargo, would you please introduce yourself
- 17 to the Court by stating your full name.
- 18 A. Joseph Andrew Camargo.
- 19 Q. And, Mr. Camargo, we met previously in Menlo
- 20 Park, California, in the summer, and -- when I took your
- 21 deposition. How are you doing today?
- 22 A. I am doing fine, thank you.
- 23 Q. I will let you know that if we look at any
- 24 documents this morning, there are paper copies in a
- 25 binder placed on the table next to you, but I will let

- 1 you know if you need to take a look at those.
- 2 A. Okay.
- 3 MS. PEAY: Your Honor, Mr. Camargo is a former
- 4 employee of Impax, the Respondent in this case, and
- 5 under your order of October 18, 2017, Mr. Camargo is an
- 6 adverse witness and subject to examination by leading
- 7 questions.
- JUDGE CHAPPELL: Okay, thank you.
- 9 MS. PEAY: Thank you, Your Honor.
- 10 BY MS. PEAY:
- 11 Q. Mr. Camargo, you were previously employed by
- 12 Impax?
- 13 A. Yes.
- Q. From March 2002 through December 2011?
- 15 A. That's correct.
- 16 Q. You currently have a consulting agreement with
- 17 Impax. Is that right?
- 18 A. Yes.
- 19 Q. You are being compensated for certain services
- 20 related to this litigation under that consulting
- 21 agreement.
- 22 A. That's true.
- 23 O. You are being compensated \$500 an hour for
- 24 services performed under the consulting agreement?
- 25 A. Yes.

- 1 Q. Including reasonable and necessary time spent in
- 2 travel?
- 3 A. Yes.
- 4 Q. You were deposed in this litigation in August of
- 5 2017.
- 6 A. I believe that was correct.
- 7 Q. And you were compensated for the time you spent
- 8 preparing for that deposition?
- 9 A. Yes.
- 10 Q. And the time you spent testifying during that
- 11 deposition?
- 12 A. Yes.
- 13 Q. Are you being compensated for time spent
- 14 preparing for your testimony in this trial?
- 15 A. Yes.
- Q. Are you being compensated for your time
- 17 testifying today?
- 18 A. Yes.
- 19 Q. You were represented by Mr. Hendricks of
- 20 O'Melveny & Myers at your deposition in August. Is that
- 21 right?
- 22 A. Yes.
- Q. At the time of your deposition, Mr. Hendricks
- 24 represented Impax, too.
- 25 A. That's my understanding.

- 1 Q. And you met with Mr. Hendricks to prepare for
- 2 that deposition?
- 3 A. Yes.
- 4 JUDGE CHAPPELL: Let me ask a question. When
- 5 you ask this witness if he's being compensated, do you
- 6 mean above and beyond any salary? For example, you and
- 7 I are also being compensated today. Is that correct?
- 8 MS. PEAY: I am being compensated today, and I
- 9 understand you are being compensated today, too.
- 10 JUDGE CHAPPELL: I would hope you are. Yes,
- 11 yes.
- MS. PEAY: My question to Mr. Camargo is whether
- 13 he's being compensated under the consulting agreement at
- 14 \$500 per hour, but I can make that clear.
- 15 JUDGE CHAPPELL: Right, because that wasn't
- 16 clear.
- 17 MS. PEAY: Thank you.
- 18 BY MS. PEAY:
- 19 Q. Mr. Camargo, are you being compensated \$500 an
- 20 hour for your time spent testifying today?
- 21 A. Yes.
- 22 Q. And, Mr. Camargo, were you compensated \$500 per
- 23 hour for your time spent preparing for your testimony
- 24 today?
- 25 A. Yes.

- 1 Q. Is the compensation paid to you under the
- 2 consulting agreement from Impax?
- 3 A. Yes.
- 4 Q. I'd like to now turn to your time at Impax. You
- 5 started as senior director of supply chain in March of
- 6 2002?
- 7 A. It was actually senior director of materials
- 8 management, yes.
- 9 O. You started as senior director of materials
- 10 management in March 2002, correct?
- 11 A. That's correct.
- 12 Q. And you were eventually promoted to vice
- 13 president of supply chain?
- 14 A. Eventually, yes.
- 15 Q. And you were the vice president of supply chain
- 16 for your -- approximately your last five years with
- 17 Impax?
- 18 A. That's correct.
- 19 Q. So that went through 2011?
- 20 A. Yes.
- 21 Q. You were the vice president of supply chain
- 22 during the 2009 to 2011 time frame, correct?
- 23 A. That's correct.
- Q. As vice president of supply chain, you led the
- 25 supply chain group?

- 1 A. That's correct.
- Q. At a high level -- I'm sorry, let me ask a
- 3 better question.
- 4 What is supply chain, Mr. Camargo?
- 5 A. The Supply Chain Department's responsibilities
- 6 were planning, purchasing, warehouse and inventory
- 7 control, and logistics.
- 8 Q. Did you also have responsibility, as vice
- 9 president of supply chain, for managing third-party
- 10 partnerships?
- 11 A. Yes.
- 12 Q. What type of third-party partnerships?
- 13 A. There were various arrangements. We had
- 14 contract manufacturers that we had make some of the
- 15 products that we had developed. We also had partnership
- 16 deals with companies who manufacture products and ship
- 17 them to us for finishing and distribution. Those were
- 18 the two main types of arrangements.
- 19 Q. I'd like to ask you more about some of the areas
- 20 of your responsibility as vice president of supply
- 21 chain.
- JUDGE CHAPPELL: Hold on a second.
- 23 (Pause in the proceedings.)
- JUDGE CHAPPELL: Go ahead.
- MS. PEAY: Thank you, Your Honor.

- 1 BY MS. PEAY:
- 2 Q. Purchasing includes procuring all the
- 3 ingredients necessary to make the finished drug product.
- 4 Is that right?
- 5 A. That's correct.
- 6 Q. And that includes procuring or purchasing active
- 7 ingredients?
- 8 A. That's correct.
- 9 Q. As well as purchasing excipients?
- 10 A. Yes.
- 11 Q. You also had responsibility for planning in your
- 12 role as vice president of supply chain, correct?
- 13 A. Yes.
- Q. Planning includes long-term capacity-related
- 15 planning activities. Is that right?
- 16 A. Yes, right.
- 17 Q. The purpose of the long-term capacity planning
- 18 was to make sure that Impax had the capacity to support
- 19 the products it intended to make in the future?
- 20 A. That's correct.
- Q. Planning also included a routine monthly
- 22 process?
- 23 A. Yes.
- Q. The monthly planning process typically uses
- 25 about an 18-month planning horizon?

- 1 A. Yes.
- 2 O. And an 18-month planning horizon includes the
- 3 products that Impax expects manufacturing operations to
- 4 produce to support the sales forecast over the next 18
- 5 months.
- 6 A. That's correct.
- 7 O. Planning also included scheduling of the
- 8 manufacturing operation?
- 9 A. There -- that was part of it during a portion of
- 10 my time there. At some point -- I don't recall exactly
- 11 when -- that responsibility was moved over to the
- 12 manufacturing group to schedule their own shop floor,
- 13 which was like a two-week horizon.
- 14 Q. Was scheduling of the manufacturing operation
- 15 one of your responsibilities in 2009?
- 16 A. I think at that point they were scheduling the
- 17 shop floor themselves, but we provided the monthly
- 18 schedule that you referred to earlier.
- 19 Q. And was planning for the scheduling and
- 20 manufacturing operation, was that under your
- 21 responsibilities in 2010?
- 22 A. No. Once it moved to manufacturing, they took
- 23 care of it from that point forward.
- Q. Part of the scheduling of the manufacturing
- 25 operation is to make sure that the plan fits within

- 1 Impax's capacity. Is that right?
- 2 A. Yes.
- 3 Q. Impax's capacity is measured in terms of labor
- 4 hours?
- 5 A. In part, yes.
- 6 Q. Is it also measured in terms of the machine
- 7 constraints?
- 8 A. Yes, that is correct.
- 9 Q. You're familiar with the term "load"?
- 10 A. Yes.
- 11 Q. And load is how many hours it takes to make a
- 12 product?
- 13 A. That would be a factor in calculating what the
- 14 total load is.
- 15 O. Are there other factors?
- 16 A. Sure.
- 17 Q. What are those factors?
- 18 A. The other factors that determine what the load
- 19 is is how much of each product that you are going to
- 20 make, multiplied by what it takes to make each of those
- 21 products, and that is in terms of both the labor load
- 22 that you were referring to but also the load on the
- 23 machines that the products go through.
- Q. There are some months when the load exceeds the
- 25 capacity?

- 1 A. That happens, yes.
- 2 O. So that means that there are some months in
- 3 which the number of hours to make the products --
- 4 necessary to make the products exceeds the number of
- 5 labor hours available?
- 6 A. From the initial plan, yes, but our
- 7 responsibility is to create an alternate plan that does
- 8 fit.
- 9 Q. In those circumstances where the number of hours
- 10 to make the products exceeds the number of labor hours
- 11 available in the initial plan, the supply chain group
- 12 first tries to increase the capacity?
- 13 A. If that's feasible, but most often it's not
- 14 within that monthly planning process. If the load is
- 15 immediate, there's not much you can do about the
- 16 capacity at that point.
- 17 Q. If you can't increase the capacity, you figure
- 18 out what to take out of the schedule to make the actual
- 19 plan fit with the available capacity?
- 20 A. Yes.
- 21 Q. In your experience at Impax, there were months
- 22 when you had to take products off the plan and push them
- 23 to another month because of capacity constraints?
- 24 A. That's correct.
- 25 JUDGE CHAPPELL: I want to make sure the record

- 1 is clear, sir. You said that scheduling and
- 2 manufacturing operation was part of your job, and then
- 3 that responsibility was moved over to another group. Is
- 4 that correct?
- 5 THE WITNESS: Yes, Your Honor. What I was
- 6 referring to there was a very short-term schedule, in
- 7 other words, what you do -- what manufacturing was going
- 8 to do day by day for the next couple of weeks, versus
- 9 establishing a monthly schedule, which was always my
- 10 department's responsibility. And that's the schedule
- 11 she's referring to where you're balancing the load
- 12 against the capacities in the monthly schedule.
- 13 JUDGE CHAPPELL: So what you're telling us now
- 14 is -- what you're telling us about is something that was
- 15 still your job at the time you were there.
- 16 THE WITNESS: That's correct.
- 17 JUDGE CHAPPELL: All right, thank you. One
- 18 other thing, does Impax or did Impax -- you are gone
- 19 now, correct?
- THE WITNESS: That's correct, yes.
- 21 JUDGE CHAPPELL: Did they ever farm out
- 22 manufacturing or always make their own drugs?
- 23 THE WITNESS: Yes, Your Honor. We did have
- 24 situations where capacity was less than what we wanted
- 25 to have, and we chose to move out some of that to

- 1 contract manufacturers. That's a longer term
- 2 requirement, takes time to make that happen, so we did
- 3 do some of that, and as I responded earlier, we had
- 4 contract manufacturers that took on some of that load.
- 5 That's not something that we could do in the monthly
- 6 cycle, though. We couldn't just decide, okay, let's
- 7 move some of that to somebody else.
- 8 JUDGE CHAPPELL: Was the Opana drug ever farmed
- 9 out for manufacture?
- 10 THE WITNESS: Not during the time that I was
- 11 there.
- 12 JUDGE CHAPPELL: All right, thank you.
- Go ahead.
- MS. PEAY: Thank you, Your Honor.
- 15 BY MS. PEAY:
- 16 Q. Supply chain also coordinated with marketing in
- 17 planning for products?
- 18 A. That's correct.
- 19 Q. Marketing provided sales projections for new and
- 20 existing products?
- 21 A. Yes.
- 22 Q. And the sales -- and these sales projections
- 23 included providing information about launch timing for
- 24 new products?
- 25 A. That's correct.

- 1 Q. And providing projected sales volumes for new
- 2 and existing products?
- 3 A. Yes.
- 4 Q. Your job -- one of your jobs as vice president
- 5 of supply chain was to ensure that you could meet the
- 6 launch dates supplied by marketing?
- 7 A. Yes.
- 8 Q. And to -- and one of your jobs as vice president
- 9 of supply chain was to ensure that you could meet the
- 10 sales volume requirements for new and existing products?
- 11 A. Yes.
- 12 Q. I'd now like to focus specifically on how the
- 13 supply chain group prepares for the launch of a new
- 14 product. Every month marketing provides the supply
- 15 chain group with a forecast for the next 18 months?
- 16 A. That's correct.
- 17 Q. The supply chain group bases its launch planning
- 18 off of the monthly -- these monthly forecasts?
- 19 A. Yes.
- 20 Q. And the supply chain group would generally kick
- 21 off the actual prelaunch preparation activities when a
- 22 product falls within the 18-month window?
- 23 A. When the first month of sales in the forecast
- 24 falls within the 18-month window, yes.
- 25 Q. The supply chain group has responsibility for

- 1 the 18-month planning process, correct?
- 2 A. Yes.
- 3 Q. And as vice president of supply chain, you
- 4 oversaw the 18-month planning process.
- 5 A. I'm sorry. Can you ask that again?
- 6 Q. Certainly.
- 7 And as vice president of supply chain, you
- 8 oversaw the 18-month planning process.
- 9 A. Yes, I did.
- 10 Q. Once a generic product enters the 18-month
- 11 planning window, the supply chain group enters
- 12 information about the product into Impax's ERP system?
- 13 A. Yes.
- Q. ERP stands for enterprise resource planning?
- 15 A. That's correct.
- 16 Q. What is an ERP system, Mr. Camargo?
- 17 A. It's a computer system that allows a company to
- 18 plan many aspects, including the purchasing, the
- 19 planning, execution of shop floor activities, financials
- 20 associated with paying suppliers, distribution of the
- 21 product, collection of revenue from customers, many
- 22 aspects, depending on what you choose to use it for. We
- 23 used it in the context of this as our system for
- 24 planning and purchasing of products.
- 25 Q. Impax's ERP system was called PRMS during the

- 1 2009 to 2010 time frame?
- 2 A. Yes.
- 3 Q. Do you know what PRMS stands for?
- 4 A. I don't recall specifically. It was an acronym
- 5 when it was first developed. I don't remember it.
- 6 Q. The supply chain group would enter information
- 7 about how the products were made into the ERP system,
- 8 correct?
- 9 A. That's correct.
- 10 Q. And the supply chain group would enter
- 11 information regarding how large the batch sizes are
- 12 going to be.
- 13 A. That's correct.
- 14 Q. And the supply chain group would enter
- 15 information about what types of materials were required
- 16 to make the product?
- 17 A. Yes.
- 18 Q. And the supply chain group would enter
- 19 information about the intended launch date into the ERP
- 20 system.
- 21 A. Yes.
- Q. Based on this information, the supply chain
- 23 group used the ERP system to plan for the materials
- 24 needed to make the product?
- 25 A. The ERP system was a tool that we used, not the

- 1 only tool.
- Q. The supply chain group used the ERP system to
- 3 determine how much capacity Impax will need to make the
- 4 product?
- 5 A. Yes, in part. Again, it was a tool for capacity
- 6 planning, but not the only one.
- 7 O. And the supply chain group used the ERP system
- 8 to -- as a tool to determine all the other milestone
- 9 dates that you would need to accomplish to be ready to
- 10 launch on the intended launch date. Is that correct?
- 11 A. No, that's not correct.
- 12 Q. Did you use another tool to determine the
- 13 milestone dates you would need to accomplish to be ready
- 14 to launch?
- 15 A. Yes.
- 16 Q. What tool did you use?
- 17 A. We used an Excel spreadsheet that I managed
- 18 called the Product Launch Checklist.
- 19 Q. The supply chain group was responsible for
- 20 ensuring that it does all of the necessary preparatory
- 21 activities to get to the point where Impax is
- 22 launch-ready as targeted by the management.
- 23 A. The supply chain group wasn't responsible for
- 24 executing all the tasks, but we were responsible for
- 25 overseeing and coordinating the execution of those

- 1 tasks.
- O. I'd like to turn now to discuss the Product
- 3 Launch Checklist that you just referred to a moment ago
- 4 that you used to keep track of the status of launch
- 5 preparations.
- 6 As vice president of supply chain, you
- 7 maintained a checklist of significant activities that
- 8 needed to be completed to ensure that Impax was
- 9 launch-ready by the date provided by Impax management?
- 10 A. That's correct.
- 11 O. And just so we're all clear, that was called the
- 12 Product Launch Checklist?
- 13 A. Yes. That was the tool I used.
- 0. You created the Product Launch Checklist?
- 15 A. I did.
- 16 Q. And maintained it?
- 17 A. I did.
- 18 Q. You included all new products that fell within
- 19 the 18-month window on the Product Launch Checklist?
- 20 A. Yes.
- 21 Q. As VP of supply chain, you chaired a meeting on
- 22 a regular basis to discuss the activities listed on the
- 23 Product Launch Checklist.
- 24 A. I did.
- 25 Q. That meeting was referred to as the launch

- 1 coordination meeting?
- 2 A. That's correct.
- 3 Q. And the meeting was generally held monthly?
- 4 A. Yes.
- 5 Q. And representatives of all departments who had
- 6 responsibilities related to planning for the product
- 7 launches attended the meetings.
- 8 A. That's correct.
- 9 Q. And that included someone from marketing?
- 10 A. Yes.
- 11 Q. Someone from purchasing?
- 12 A. Yes.
- 13 Q. Someone from regulatory?
- 14 A. Yes.
- Q. As well as other groups within Impax?
- 16 A. Correct.
- 17 Q. The purpose of the launch coordination meeting
- 18 was to ascertain the status of the products listed on
- 19 the Product Launch Checklist?
- 20 A. Yes, among other things.
- 21 Q. And one of the other purposes was to ensure that
- 22 everybody had a common understanding of the planned
- 23 launch-ready dates and what things needed to be done by
- 24 when?
- 25 A. That's correct.

- 1 Q. I'd like to turn to some of the specific tasks
- 2 that, once a new product has been uploaded into the ERP
- 3 system, need to be completed to prepare to be ready to
- 4 launch a product. One task that needs to be completed
- 5 is to place a purchase order for API and unique
- 6 materials?
- 7 A. Yes.
- 8 Q. API is active pharmaceutical ingredient?
- 9 A. Yes.
- 10 Q. For oxymorphone ER, the API is oxymorphone HCL?
- 11 A. I don't recall if there's a specific salt form
- 12 of it, but, you know, there were different forms, and
- 13 that could very well be one. I don't recall.
- 14 Q. The API for oxymorphone ER was some form of
- 15 oxymorphone, correct?
- 16 A. That's correct.
- Q. Purchasing was responsible for placing purchase
- 18 orders for API?
- 19 A. Yes.
- 20 Q. And purchasing fell within the supply chain
- 21 group.
- 22 A. Yes.
- 23 O. The amount of API needed is driven first and
- 24 foremost by the monthly forecast?
- 25 A. Yes.

- Q. As well as the definition of what it takes to make the product?
- 3 A. That's correct.
- 4 Q. And whether any safety stocks are required?
- 5 A. Yes.
- 6 Q. What is a safety stock?
- 7 A. A safety stock is a predetermined amount of
- 8 inventory that you want to have in place to guard
- 9 against potential variability of either the demand for
- 10 that product or that material or the -- delays in the
- 11 supply of that product or material.
- 12 Q. I'd like to talk about the steps that must be
- 13 taken before placing a purchase order for API for a
- 14 controlled substance. A controlled substance is one
- 15 that is regulated by the DEA?
- 16 A. That's correct.
- 17 Q. Oxymorphone is a controlled substance?
- 18 A. Yes, it is.
- 19 Q. And to acquire API for a controlled substance,
- 20 you have to request quota from the DEA?
- 21 A. For that type of controlled substance, you do.
- Q. And by "that type," you're referring to
- 23 oxymorphone?
- 24 A. Yes.
- 25 Q. Quota is an amount of a controlled substance

- 1 that the DEA permits you to purchase in a particular
- 2 year?
- 3 A. Yes, for a particular purpose as well.
- 4 Q. Quota can be granted for different purposes. Is
- 5 that correct?
- 6 A. Yes.
- 7 Q. Including research and development?
- 8 A. Yes.
- 9 Q. Or commercial sale?
- 10 A. Yes.
- 11 O. You can only purchase as much API as the amount
- 12 of quota you've been granted in that given year. Is
- 13 that correct?
- 14 A. That's correct.
- 15 Q. To prepare for a product launch of a controlled
- 16 substance, the quota would need to be granted for
- 17 commercial manufacturing -- commercial manufacturing and
- 18 sale, correct?
- 19 A. Yes.
- 20 Q. We have just been talking about purchasing API
- 21 and requesting quota from the DEA. I would like to
- 22 discuss another task that needs to be completed before a
- 23 product can be ready to launch. Are you familiar with
- 24 process validation?
- 25 A. Yes.

- Q. Process validation is an FDA requirement that
- 2 you have to prove that your manufacturing process is
- 3 repeatable and makes the product in a satisfactory
- 4 manner?
- 5 A. That's correct.
- Q. Process validation has to be complete before the
- 7 product is launched?
- 8 A. Yes.
- 9 Q. The process validation batches have to be
- 10 tested?
- 11 A. Yes.
- 12 Q. And you have to document that the product was
- 13 successfully validated.
- 14 A. Yes.
- 15 Q. That documentation is -- may also be referred to
- 16 as approving the manufacturing PV summary?
- 17 A. We referred to it as a PV summary report.
- 18 Q. During your time as Impax's VP of supply chain,
- 19 Impax typically planned to sell the process validation
- 20 batches commercially. Is that correct?
- 21 A. That's correct.
- 22 Q. But sometimes the process validation batches are
- 23 not enough to meet the projected demand at launch?
- 24 A. That's true.
- 25 O. So Impax would need to manufacture additional

- 1 product to have enough available to meet the expected
- 2 needs when you launch the product.
- 3 A. Yes.
- 4 Q. This additional product is referred to as launch
- 5 inventory or launch inventory build?
- 6 A. That's correct.
- 7 O. The launch inventory build is the additional
- 8 product manufactured when the process validation batches
- 9 are not enough to meet your expected needs to launch the
- 10 product, correct?
- 11 A. That's correct, and they would be manufactured
- 12 after -- they would be manufactured after the PV summary
- 13 report is signed off on.
- 14 Q. We have been discussing the process for planning
- 15 for the launch of a product generally. I would like to
- 16 now turn to the process the supply chain group followed
- 17 to prepare to be launch-ready for Impax's oxymorphone ER
- 18 product, okay?
- 19 A. Okay.
- 20 Q. During your time at Impax, Impax was planning
- 21 for the launch of a generic oxymorphone ER product?
- 22 A. Yes.
- 23 Q. And as VP of supply chain, you oversaw the
- 24 planning for the launch of a generic oxymorphone ER
- 25 product.

- 1 A. Yes.
- Q. And just so we're clear as we go along, within
- 3 Impax, was oxymorphone ER sometimes referred to as just
- 4 oxymorphone?
- 5 A. Yes.
- 6 Q. And sometimes by the abbreviation OXM?
- 7 A. Yes.
- 8 Q. So you'll know what I mean if I refer to either
- 9 of those shorthands?
- 10 A. Yes.
- 11 O. Thank you.
- Oxymorphone ER is the generic name for Opana ER?
- 13 A. Yes.
- 14 Q. And Opana ER is a pharmaceutical product that
- 15 was manufactured and marketed by Endo Pharmaceuticals.
- 16 A. That's correct.
- 17 Q. The supply chain group began planning for the
- 18 launch of oxymorphone -- let me ask a better question.
- 19 In 2009, the supply chain group began planning
- 20 for the launch of oxymorphone ER.
- 21 A. Yes.
- 22 Q. The supply chain group's planning for
- 23 oxymorphone ER began when the product entered the
- 24 18-month planning window, correct?
- 25 A. I believe so.

- Q. And the supply chain group learns about which
- 2 products are within the 18-month planning window because
- 3 it receives forecasts from marketing on a monthly basis.
- 4 A. In part.
- 5 Q. A member of marketing emails the 18-month
- 6 planning window forecast to the supply chain group each
- 7 month?
- 8 A. Yes.
- 9 Q. In 2009 and 2010, Mr. Kevin Sica was responsible
- 10 for sending those monthly forecasts to the supply chain
- 11 group?
- 12 A. Yes.
- Q. And Mr. Sica was in marketing?
- 14 A. Yes.
- 15 Q. Mr. Camargo, would you please pick up your
- 16 binder and take a look at Exhibit CX 2891.
- 17 While you are doing that, I will state that this
- 18 exhibit is included in JX 2 and has been admitted in
- 19 evidence. The exhibit is not subject to Your Honor's in
- 20 camera ruling.
- 21 You received this email from Mr. Sica?
- 22 A. I'm sure I did.
- Q. Is the answer yes, that you received the email
- 24 from Mr. Sica?
- 25 A. I'm sure I did. I can't recall the receipt of

- 1 it, but it was addressed to me and it was something I
- 2 saw routinely.
- 3 Q. And the email is dated June 5th, 2009?
- 4 A. Yes.
- 9 Q. Ms. Wint, would you please put the first page of
- 6 CX 2891 up on the screen.
- 7 Mr. Sica is sending the type of monthly forecast
- 8 that the supply chain group puts into the ERP system?
- 9 A. Yes.
- 10 Q. The supply chain group plans for the launch of
- 11 new generic products based on the information provided
- 12 in this type of monthly forecast.
- 13 A. Yes.
- Q. In his email, Mr. Sica wrote that oxymorphone,
- 15 four strengths, entered the forecast horizon in June
- 16 2010 with an assumed at-risk launch.
- 17 Do you see that?
- 18 A. I do.
- 19 Q. Mr. Camargo, an at-risk launch is a launch while
- 20 there is outstanding, unsettled patent litigation?
- 21 A. Yes.
- 22 Q. Turning to page CX 2891-003, this is a worksheet
- 23 labeled "June Forecast Bottles"?
- 24 Is this a forecast -- is this a worksheet
- 25 labeled "June Forecast Bottles"?

- 1 A. Yes. I'm sorry, I didn't realize that was a
- 2 question.
- 3 Q. "Bottles" refers to the number of bottles of a
- 4 particular product that are forecast to be sold?
- 5 A. That's correct.
- 6 Q. Ms. Wint, can you please pull up the lines for
- 7 oxymorphone ER.
- 8 And, Mr. Camargo, in this June 2009 forecast,
- 9 there's a line for oxymorphone ER, 5 milligrams. Do you
- 10 see that?
- 11 A. I do.
- 12 O. And in this June 2009 forecast, sales for the
- 13 oxymorphone ER 5-milligram begin in June 2010. Is that
- 14 correct?
- 15 A. That's correct.
- 16 Q. In this forecast, there is also a line for
- 17 oxymorphone ER 10 milligrams as well?
- 18 A. Yes.
- 19 Q. And 20 milligrams?
- 20 A. Yes.
- Q. And 40 milligrams?
- 22 A. Yes.
- Q. And this June -- in this June 2009 forecast, the
- 24 sales begin in June 2010 for the -- for all of those
- 25 strengths of oxymorphone ER?

- 1 A. Yes.
- O. You can set that exhibit aside.
- 3 Mr. Camargo, the supply chain group uploaded
- 4 this June 2009 forecast into PRMS, correct?
- 5 A. I'm sure we did.
- 6 Q. It was the supply chain group's practice to
- 7 upload these monthly forecasts into PRMS, correct?
- 8 A. That's correct.
- 9 Q. And the supply chain group began planning to be
- 10 ready for the launch of these four strengths of
- 11 oxymorphone ER in June 2010.
- 12 A. I can't say we began in June 2010, but certainly
- 13 by then we were, if not sooner.
- 14 Q. I can ask a better question.
- 15 Based on this June -- based on this June 2009
- 16 forecast, the supply chain group began planning to be
- 17 ready for the launch of four strengths of oxymorphone ER
- 18 in June of 2010.
- 19 A. I can certainly say we would have started no
- 20 later than that date. We may have started planning
- 21 sooner than that date.
- 22 Q. And the date of launch that you were planning
- 23 for would have been June 2010.
- 24 A. At that point in time of that June 2009 email,
- 25 yes, that was the date.

- Q. As part of the planning process for oxymorphone
- 2 ER, Impax requested quota from the DEA for oxymorphone,
- 3 correct?
- 4 A. Correct -- well, I mean, let me correct one
- 5 aspect of it. The supply chain group did not directly
- 6 submit the quota request to DEA. We requested the quota
- 7 through our Regulatory Affairs Department who then, in
- 8 turn, submitted the request to the DEA.
- 9 Q. And Mr. John Anthony from the Regulatory Affairs
- 10 Department was Impax's designated DEA contact?
- 11 A. That's correct.
- 12 Q. And he was responsible for submitting quota
- 13 requests?
- 14 A. Yes.
- 15 Q. And you, in the supply chain group, provided
- 16 Mr. Anthony with information regarding how much
- 17 oxymorphone API Impax needed for the planned launch,
- 18 correct?
- 19 A. Correct.
- 20 Q. And Mr. Anthony used that information in the
- 21 request he made to the DEA for quota?
- 22 A. Yes.
- 23 Q. Impax made several requests for oxymorphone
- 24 quota for 2010, correct?
- 25 A. Yes.

- 1 Q. The first request was denied?
- 2 A. Yes.
- 3 Q. So Impax submitted another request for quota
- 4 after that first request was denied.
- 5 A. Yes.
- 6 Q. And Mr. Anthony asked you for your input
- 7 regarding how much oxymorphone API Impax needed to
- 8 manufacture enough product for process validation,
- 9 correct?
- 10 A. I know he at least asked for how much we needed
- 11 for process validation. I'm not sure if he asked only
- 12 for process validation quantities.
- 13 Q. Did he also ask for how much oxymorphone API
- 14 Impax needed to manufacture enough product for a launch
- 15 inventory build?
- 16 A. That would have been part of the requested
- 17 information, yes.
- 18 Q. And you provided him with the information he
- 19 requested?
- 20 A. Yes.
- 21 Q. Impax received additional oxymorphone quota,
- 22 correct? To be clear, in 2010.
- 23 A. Yes, during 2010.
- 24 Q. And as of March 2010, Impax had received enough
- 25 quota to complete -- to enable it to complete process

- 1 validation, correct?
- 2 A. Yes.
- 3 Q. And as of March 2010, Impax had enough quota to
- 4 enable it to manufacture some of -- part of the launch
- 5 inventory build, correct?
- 6 A. I don't recall the specific timing, but I know
- 7 at some point we got enough quota to start the launch
- 8 inventory build.
- 9 Q. At some point in time prior to June 2010, you
- 10 got enough --
- 11 A. Yes.
- 12 Q. -- quota to do part of the launch inventory
- 13 build?
- 14 A. Yes.
- 15 Q. Impax used the quota it received from the DEA
- 16 for oxymorphone ER?
- 17 A. You would have to put a time frame around that
- 18 question.
- 19 Q. I can ask a better question.
- Impax used the quota that it received from the
- 21 DEA as of March 2010, correct?
- 22 A. Yes. We purchased that material that was
- 23 authorized.
- Q. So Impax purchased all of the API it was
- 25 authorized to purchase under the oxymorphone quota it

- 1 had received as of March 2010.
- 2 A. Yes, I believe so.
- 3 Q. Mr. Camargo, I'd like you to take a look -- if
- 4 you could pick up your binder and take a look at
- 5 CX 2898.
- 6 While you're doing that, I will state that this
- 7 exhibit is included in JX 2 and has been admitted in
- 8 evidence, and it's not subject to the in camera ruling.
- 9 Mr. Camargo, this is an email you sent to a
- 10 Mr. Todd Engle, correct?
- 11 A. Correct.
- Q. And you sent this email on May 12th, 2010?
- 13 A. Yes.
- 14 Q. Mr. Engle was director of sales and marketing?
- 15 A. He was a director in the sales and marketing
- 16 group. I don't know his exact title.
- Q. And this is -- this is an email you sent to
- 18 Mr. Engle regarding input he had requested on some new
- 19 products?
- 20 A. Yes.
- 21 Q. Including oxymorphone ER?
- 22 A. Yes.
- Q. Ms. Wint, can you please put the first page of
- 24 CX 2898 up on the screen.
- 25 Mr. Camargo, let me direct you to the section of

- 1 your email labeled "Oxymorphone." Do you see that?
- 2 A. I do.
- 3 Q. Sir, as of the date of this email, May 12th,
- 4 2010, Impax had purchased all of its API quota for
- 5 oxymorphone, correct?
- 6 A. Correct.
- 7 Q. And Impax had enough to make two lots of
- 8 20-milligram and six lots of 40-milligram oxymorphone
- 9 ER, correct?
- 10 A. Correct.
- 11 Q. And those two lots of 20-milligram and six lots
- 12 of 40-milligram were intended to be part of the
- 13 inventory build, correct?
- 14 A. Correct.
- Q. So that's eight lots total of the inventory
- 16 build.
- 17 A. Yes.
- Q. As of the date of this email, May 12th, 2010,
- 19 the process validation batches had been manufactured.
- 20 A. Yes.
- Q. And you expected the PV summary report to be
- 22 signed off by May 18th?
- 23 A. Yes.
- Q. And once the PV summary report has been signed
- 25 off on, the process validation is complete?

- 1 A. Yes.
- Q. And the standard practice at Impax in 2010 was
- 3 to hold off on beginning a launch inventory build until
- 4 the PV summary report had been signed off on, correct?
- 5 A. Yes. We did not start them until after a PV
- 6 summary report was signed off.
- 7 O. So as of May 12th, 2010, you were waiting for
- 8 the go-ahead from senior management?
- 9 A. For the oxymorphone ER, yes.
- 10 Q. And if you received the go-ahead from senior
- 11 management for oxymorphone ER once the process
- 12 validation summary report was signed off on, you were
- 13 prepared from the supply chain standpoint to commence
- 14 with the launch inventory build.
- 15 A. That's correct.
- 16 Q. Let me direct you to the third bullet under
- 17 "Oxymorphone." John Anthony is the individual from
- 18 regulatory affairs you were discussing earlier?
- 19 A. Right.
- 20 Q. So Impax made another request for oxymorphone
- 21 quota in mid-April of 2010?
- 22 A. Yes.
- Q. So as of the date of this email, May 12th, 2010,
- 24 you had enough API to do an initial launch of
- 25 oxymorphone ER.

- 1 A. Yes, with just a bit under our target amount of
- 2 three months of inventory.
- 3 Q. But you needed additional quota to sustain the
- 4 product after launch.
- 5 A. Correct.
- Q. And as of the date of this email, May 12th, you
- 7 had not heard back from the DEA regarding the mid-April
- 8 request for additional quota.
- 9 A. Correct.
- 10 Q. You can set this exhibit aside.
- 11 Mr. Camargo, I'd like to turn now to the
- 12 progress you made by May 2010 to prepare to be ready to
- 13 launch oxymorphone ER. Earlier, you testified that you
- 14 created and maintained a Product Launch Checklist,
- 15 correct?
- 16 A. Yes.
- 17 Q. And you circulated the Product Launch Checklist
- 18 in advance of product launch coordination meetings.
- 19 A. Yes.
- Q. You tracked the progress of your preparations to
- 21 be launch-ready for oxymorphone ER on the Product Launch
- 22 Checklist, right?
- 23 A. Yes.
- Q. Mr. Camargo, can you please take a look in your
- 25 binder at CX 3078.

- While you're doing that, I'll state that this
- 2 exhibit is included in JX 2 and has been admitted in
- 3 evidence. This exhibit is not subject to the in camera
- 4 ruling.
- 5 Mr. Camargo, this is an email and an attachment
- 6 that you sent on May 11th, 2010?
- 7 A. Yes.
- 8 Q. And the attachment is the May 11th, 2010,
- 9 version of the Product Launch Checklist?
- 10 A. Yes.
- 11 Q. Ms. Wint, can you please put the first page of
- 12 CX 3078 up on the screen.
- 13 You sent this checklist in advance of the May
- 14 11th, 2010, product launch coordination meeting?
- 15 A. Yes.
- 16 Q. I would like to direct your attention to the
- 17 attachment, page CX 3078-003. Ms. Wint, can you please
- 18 call up the planned launch-ready date.
- 19 The planned launch-ready date is the date by
- 20 which you were aiming to complete all the activities
- 21 necessary so that Impax is launch-ready, correct?
- 22 A. That's correct.
- 23 Q. And the planned launch-ready date, as of this
- 24 May 11th, 2010, Product Launch Checklist for oxymorphone
- 25 5-, 10-, 20-, and 40-milligram strengths listed --

- 1 listed at the top of that column, was the end of May?
- 2 A. Correct.
- Q. And the default planned launch-ready date is
- 4 three months before the launch target date, correct?
- 5 A. Yes, typically.
- 6 Q. The launch target date is provided by marketing?
- 7 A. Yes, in part. They are not the only
- 8 participants in deciding what that date should be, but
- 9 they chair a meeting where that type of thing is
- 10 discussed and agreed upon.
- 11 O. And the launch target date is the date of the
- 12 planned actual product launch?
- 13 A. Correct.
- 14 Q. Sometimes the launch target date is the
- 15 anticipated date of FDA approval?
- 16 A. Yes.
- 17 Q. But the launch target is not always the
- 18 anticipated FDA approval date.
- 19 A. That's correct.
- Q. Also, in some circumstances, the planned
- 21 launch-ready date is less than the default of three
- 22 months before the launch target date.
- 23 A. That's correct.
- Q. Ms. Wint, can you please call out the columns on
- 25 oxymorphone ER.

- 1 Mr. Camargo, do you see the column that's
- 2 labeled "Task Description"?
- 3 A. Yes.
- 4 O. That's the column that identifies the
- 5 significant tasks that generally need to be completed to
- 6 be ready to launch a product?
- 7 A. Yes.
- 8 O. There are 51 tasks listed here?
- 9 A. Correct.
- 10 Q. Do you also see the column for oxymorphone ER
- 11 5-, 10-, 20-, and 40-milligram strengths?
- 12 A. Yes.
- 13 Q. That's the column that tracks the progress of
- 14 your product launch preparations for those strengths of
- 15 oxymorphone ER?
- 16 A. Correct.
- 17 Q. Now, if you look at that column under the -- for
- 18 the 5, 10, 20, and 40 oxymorphone ER strengths, you see
- 19 a lot of Xs.
- 20 A. Yes.
- 21 O. And an X in Excel means that a task is
- 22 completed?
- 23 A. Correct.
- Q. So task 20 says "Place purchase order" -- or
- 25 "Place PO for API and unique materials"?

- 1 A. Correct.
- O. And an X next to that means that task had been
- 3 completed as of May 11, 2010?
- 4 A. Yes.
- 5 Q. And task 32, for example, says "Validation
- 6 batches started."
- 7 A. Yes.
- 8 Q. And validation batches are -- can also be
- 9 referred to as process validation batches?
- 10 A. Yes.
- 11 O. And an X next to that task means that the
- 12 process validation batches had been started as of May
- 13 11, 2010.
- 14 A. Correct.
- 15 Q. Three question marks next to a task means that
- 16 you do not have enough information to populate the field
- 17 yet?
- 18 A. That's correct.
- 19 Q. And there are only a couple of tasks for
- 20 oxymorphone ER 5-, 10-, 20-, and 40-milligram strengths
- 21 for which there are three question marks, correct?
- 22 A. Yes.
- Q. In your checklist, the designation of "TBD"
- 24 means that the timing of the completion of that task is
- 25 not yet defined?

- 1 A. That is correct.
- 2 O. You don't see -- there aren't any TBDs for
- 3 oxymorphone 5, 10, 20, and 40 milligrams as of the date
- 4 of this version of the Product Launch Checklist, are
- 5 there?
- 6 A. No, there are not.
- 7 O. The dates that are listed on the Product Launch
- 8 Checklist are typically the date by which you plan to
- 9 complete the task?
- 10 A. Yes.
- 11 Q. And those dates may be based on your backwards
- 12 planning from the launch date provided by marketing?
- 13 A. Yes.
- 14 Q. And they may be updated during a -- during a
- 15 launch coordination meeting to be the date when you are
- 16 now actually expecting to complete the task?
- 17 A. Yes.
- 18 O. As of the -- according to this Product Launch
- 19 Checklist, the validation batches had been manufactured
- 20 by April 20th?
- 21 A. That's not correct. That was the target date
- 22 for -- that I had on this checklist as of the
- 23 publication of this premeeting status.
- Q. As of May 11th, the target to manufacture the
- 25 launch inventory was May 28th?

- 1 A. That's correct. The -- it would -- it might be
- 2 illogical sounding since it's past that date, but we
- 3 typically met once a month, so that was the last
- 4 scheduled date, and when we met, we would update that
- 5 based on the input from the different groups. So as of
- 6 that date, it may have been completed already. I just
- 7 hadn't had the meeting. This is a premeeting status.
- 8 Q. Mr. Camargo, I just want to make certain that
- 9 your testimony is clear, because my question may not
- 10 have been clear.
- 11 My question was focusing on task 40. As of this
- 12 May 11th Product Launch Checklist, the target date to
- 13 manufacture the launch inventory was May 28th. Is that
- 14 correct?
- 15 A. Yes. I'm sorry, I thought you were talking
- 16 about step 33.
- 17 Q. Thank you.
- 18 And as of the date of this Product Launch
- 19 Checklist, you expected to complete testing of the
- 20 launch inventory batches on June 11th, as reflected by
- 21 task 41.
- 22 A. Yes.
- 23 O. And as of the date of this Product Launch
- 24 Checklist, the launch-ready date indicated under task 49
- 25 was June 14th.

- 1 A. Yes.
- Q. Mr. Camargo, you can set that exhibit aside.
- 3 Impax settled litigation with Endo on June 8th,
- 4 2010.
- 5 A. I don't recall the date. I know there was a
- 6 settlement with Endo.
- 7 Q. Do you recall that Impax settled with Endo in
- 8 June of 2010?
- 9 A. Again, I don't recall a specific date, but in
- 10 that time frame, yes.
- MS. PEAY: Your Honor, the parties have
- 12 stipulated to the date of the settlement between Impax
- 13 and Endo in JX 001, fact stipulation number 19.
- 14 JUDGE CHAPPELL: Okay, but the witness has
- 15 already told you he doesn't know the date.
- 16 BY MS. PEAY:
- 17 Q. So, Mr. Camargo --
- 18 JUDGE CHAPPELL: In fact, I don't know that he
- 19 knows anything about the litigation or the settlement.
- 20 MS. PEAY: Thank you, Your Honor.
- 21 JUDGE CHAPPELL: That means I haven't heard a
- 22 foundation.
- MS. PEAY: Thank you, Your Honor.
- 24 BY MS. PEAY:
- 25 Q. Mr. Camargo, in your position as VP of supply

- 1 chain at Impax, were you aware of whether Impax was
- 2 engaged in litigation with Endo regarding its
- 3 oxymorphone ER product?
- 4 A. I do not believe I was aware of that prior to
- 5 the settlement.
- 6 Q. You weren't aware that there was a litigation
- 7 ongoing between Impax and Endo?
- 8 A. I was aware of the open litigation, yes.
- 9 Q. And -- and that litigation concerned Impax's
- 10 oxymorphone ER product?
- 11 A. Yes.
- 12 Q. And that was a patent litigation?
- 13 A. That's my understanding, yes.
- 14 O. And so --
- JUDGE CHAPPELL: Let's stick to what you know,
- 16 sir, not your understanding. Tell us what you know, not
- 17 what you understand.
- 18 THE WITNESS: I -- I can't say I knew absolutely
- 19 for certain. I wasn't privy to the actual lawsuit
- 20 itself.
- 21 BY MS. PEAY:
- 22 Q. And, Mr. Camargo, are you -- did Impax settle
- 23 the litigation with Endo?
- 24 A. Yes.
- 25 Q. And did Impax settle the litigation with Endo in

- 1 June of 2010?
- 2 A. In that time frame, yes. I don't know the exact 3 date.
- 4 Q. As a result of Impax's settlement with Endo, you
- 5 halted work on preparing to launch oxymorphone ER?
- 6 A. That's correct.
- 7 Q. In your role as VP of supply chain, you sent
- 8 monthly reports to your boss, Mr. Charles Hildenbrand?
- 9 A. Yes.
- 10 Q. And in those reports, you reported on the key
- 11 things associated with the prior month's activity?
- 12 A. Yes.
- 13 Q. Okay. Mr. Camargo, can you please take a look
- 14 at CX 2905 in your binder.
- This exhibit is included in JX 2, has been
- 16 admitted in evidence, and is not subject to Your Honor's
- 17 in camera ruling.
- 18 Mr. Camargo, you are a sender and a recipient in
- 19 this email chain. Is that correct?
- 20 A. Yes.
- Q. Dated June 8th through June 11th, 2010.
- 22 A. Yes.
- Q. And in the last email on June 11th, 2010, you
- 24 sent a monthly report to your boss, Mr. Hildenbrand?
- 25 A. Yes.

- 1 Q. And these are reports that you sent to
- 2 Mr. Hildenbrand on a regular basis?
- 3 A. Yes.
- 4 Q. Ms. Wint, can you please put the first page of
- 5 CX 2905 up on the screen.
- 6 This particular report that you were sending to
- 7 Mr. Hildenbrand was for activities in May of 2010,
- 8 correct?
- 9 A. Correct.
- 10 Q. If you would please turn to CX 2905-003. Let me
- 11 direct you to number 2 under "Other Highlights."
- 12 Mr. Camargo, you wrote this report?
- 13 A. Yes.
- Q. Okay. And number 2, under "Other Highlights,"
- 15 reads: "The Oxymorphone PV Summary report was
- 16 approved." Do you see that?
- 17 A. Yes.
- 18 Q. And the approval of the PV summary report was
- 19 the last step in process validation?
- 20 A. Correct.
- 21 Q. So process validation had been complete.
- 22 A. Yes.
- Q. You go on to write: "The launch inventory build
- 24 is ready to start should management give the go-ahead."
- 25 A. Yes.

- 1 Q. If Impax management had given you the go-ahead,
- 2 you were ready to start the launch inventory build?
- 3 A. Yes.
- 4 Q. You continued to write: "With the Endo
- 5 settlement in place, this project will be halted."
- 6 A. I did.
- 7 O. The Endo settlement refers to the settlement of
- 8 the patent litigation with Endo that we were just
- 9 discussing earlier?
- 10 A. Yes.
- 11 Q. So Impax halted launch preparations for
- 12 oxymorphone ER due to the settlement with Endo.
- 13 A. Yes.
- Q. Thank you, Mr. Camargo. You can put that
- 15 exhibit aside.
- 16 At the time of the settlement with Endo, Impax's
- 17 mid-April request for oxymorphone quota was still
- 18 pending with the DEA, correct?
- 19 A. I don't recall when the DEA responded to that
- 20 mid-April request.
- 21 Q. At the time of the settlement with Endo, Impax
- 22 had a request for oxymorphone quota that was still
- 23 pending with the DEA.
- 24 A. Again, I don't know when the DEA responded.
- 25 They could have responded before that date. They may

- 1 not have. I don't recall.
- Q. Mr. Camargo, you do not remember?
- 3 A. I --
- Q. Do you not remember whether Impax had a quota
- 5 request pending with the DEA at the time of Impax's
- 6 settlement with Endo?
- 7 A. No. I don't recall the status of that specific
- 8 request at that time.
- 9 Q. Might it refresh your memory if -- your
- 10 recollection if I showed you an email that you were a
- 11 recipient of that addressed the subject?
- 12 A. That would certainly help my memory.
- 13 Q. Can you take a look in your binder at CX 3081.
- 14 And, Mr. Camargo, if you can read this quietly to
- 15 yourself and let me know when you're done.
- 16 A. (Document review.) Okay.
- 17 Q. Does that refresh your recollection?
- 18 A. Well, this tells me that as of June 9th, it was
- 19 not yet -- the DEA had not yet responded to that quota
- 20 request, and we were considering withdrawing it.
- 21 Q. Thank you. You can set that aside.
- 22 The DEA did actually grant Impax additional
- 23 oxymorphone quota later in June of 2010, correct?
- 24 A. Yes, sometime subsequent to this June 9th email.
- 25 Q. But Impax had no intention of using that quota

- 1 to purchase oxymorphone API in 2010, correct?
- 2 A. Not once the Endo settlement was achieved.
- Q. And is that because after the settlement in June
- 4 2010, Impax had no plans for launching an oxymorphone
- 5 product in the calendar year 2010?
- 6 A. That's correct.
- 7 O. At the time of the settlement in June 2010,
- 8 Impax had already manufactured some quantity of
- 9 oxymorphone ER?
- 10 A. Yes.
- 11 Q. And you were asked by management to calculate
- 12 the value of that manufactured oxymorphone product?
- 13 A. Yes.
- Q. Mr. Camargo, if you would turn in your binder to
- 15 Exhibit CX 3053.
- This exhibit is included in JX 2 and has been
- 17 admitted in evidence. It is not subject to the in
- 18 camera ruling.
- 19 Mr. Camargo, you were a sender and recipient of
- 20 emails in this email chain?
- 21 A. Yes.
- Q. And this was dated June 4th, 2010?
- 23 A. Yes.
- Q. Ms. Wint, can you please put the first page of
- 25 CX 3053 up on the screen.

- 1 Mr. Camargo, who's Ray Smith?
- 2 A. Ray Smith was part of our finance team, and one
- 3 of his responsibilities was cost accounting.
- 4 Q. If you can turn to CX 3053-002.
- 5 Mr. Hildenbrand asked you, "What is the value of
- 6 the OXM PVs that we have produced so far?" Do you see
- 7 that?
- 8 A. Yes.
- 9 Q. And he's referring to oxymorphone ER -- do you
- 10 know if he's referring to oxymorphone ER process
- 11 validation batches?
- 12 A. Yes.
- 13 JUDGE CHAPPELL: What did he mean by "value,"
- 14 what it had cost the company? What did that mean
- 15 when -- she asked about value and you said yes. What
- 16 did you mean by "value"?
- 17 THE WITNESS: Your Honor, the inventory that we
- 18 have in our ERP system is carried at what's called a
- 19 standard cost, which includes the cost of all the
- 20 materials that it took to make it and the cost of all
- 21 the direct labor and a factor to account for overhead.
- 22 So the standard cost times the number of units that we
- 23 had in inventory would be the total cost.
- 24 JUDGE CHAPPELL: Anything to do with market
- 25 value or profits?

- 1 THE WITNESS: No.
- JUDGE CHAPPELL: Go ahead.
- 3 MS. PEAY: Thank you, Your Honor.
- 4 BY MS. PEAY:
- 5 Q. Back on CX 3053-001, you responded to
- 6 Mr. Hildenbrand's request for the value of the
- 7 oxymorphone ER process validation batches that had been
- 8 manufactured as of June 4th?
- 9 A. Yes.
- 10 Q. And you informed Mr. Hildenbrand that the total
- 11 value of the manufactured oxymorphone product as of June
- 12 4th at standard cost was \$1,387,883?
- 13 A. Yes.
- Q. Some of the manufactured product was in
- 15 britestock?
- 16 A. Yes.
- 17 Q. That's product that has been manufactured and
- 18 put in bottles but has not been labeled?
- 19 A. Correct.
- 20 Q. And some of the manufactured product was
- 21 finished goods?
- 22 A. Yes.
- Q. That's product that has been manufactured, put
- 24 in bottles, and has a label?
- 25 A. Yes, I believe as well as all finished packaging

- 1 ready for distribution.
- 2 O. Impax was not able to sell the manufactured
- 3 oxymorphone product, correct?
- 4 A. That's correct -- well, we were able to from an
- 5 FDA perspective but not per the settlement.
- 6 Q. Thank you. We're done with that exhibit.
- 7 Mr. Camargo, can you please turn to CX 2896 in
- 8 your binder.
- 9 This exhibit is included in JX 2 and has been
- 10 admitted in evidence and is not subject to the in camera
- 11 ruling.
- Mr. Camargo, you were the sender of this email
- 13 and attachment?
- 14 A. Yes.
- Q. Ms. Wint, can you please put CX 2896 up on the
- 16 screen, the first page.
- 17 Mr. Camargo, you were sending an email to your
- 18 boss, Mr. Hildenbrand, on August 10th, 2010?
- 19 A. Yes.
- Q. And you attach a monthly report?
- 21 A. Yes.
- 22 Q. And this monthly report is for activities in
- 23 July of 2010.
- 24 A. Yes.
- 25 Q. Can you please turn to, in the attachment,

- 1 CX 2896-002. Mr. Camargo, you -- you wrote this memo?
- 2 A. Yes.
- O. And I'd like to focus on the second chart on
- 4 this page and the text below it. This chart or table is
- 5 titled "YTD Rejects as Percentage of COGS (Target =
- 6 2.5%)." Do you see that?
- 7 A. I do.
- 8 Q. "YTD" is year to date?
- 9 A. Yes.
- 10 Q. And what is "COGS"?
- 11 A. Cost of goods sold.
- 12 Q. What did you mean when you wrote, "Target =
- 13 2.5%"?
- 14 A. Our target was that the dollar value of our
- 15 rejects that we had an -- you know, actually experienced
- 16 or anticipated would be 2.5 percent or less of the cost
- 17 of goods sold for that month.
- 18 Q. What is a reject?
- 19 A. A reject can happen for a multitude of reasons.
- 20 It would be inventory that we had on the financial books
- 21 that we no longer expected to be usable for one reason
- 22 or another.
- Q. Under the table, you wrote, "Rejects as % of
- 24 [Cost of Goods Sold]: We took a \$1.4M hit in June for
- 25 materials which became obsolete by virtue of settlement

- 1 on Oxymorphone."
- 2 A. Yes.
- 3 Q. You had manufactured oxymorphone product for a
- 4 potential launch?
- 5 A. Yes.
- 6 Q. But now that Impax had settled with Endo, it had
- 7 to destroy this oxymorphone product because it could not
- 8 be sold before its expiration date?
- 9 A. It had to be accounted for financially as likely
- 10 to be rejected. We didn't -- we didn't have to destroy
- 11 it immediately.
- 12 Q. And the materials at issue were worth about 1.4
- 13 million?
- 14 A. Yes, that was the value.
- 15 Q. These -- the rejected oxymorphone product drove
- 16 the increase of rejects, as a percentage of cost of
- 17 goods sold, above 2.5 percent, correct?
- 18 A. Yes.
- 19 Q. Which means including the \$1.4 million hit from
- 20 the rejected oxymorphone ER product, you were not
- 21 meeting your goal?
- 22 A. That's correct.
- O. You can set that exhibit aside.
- 24 While at Impax, your performance was assessed
- 25 against goals that were set for the year.

- 1 A. Yes.
- Q. Part of the performance review process involved
- 3 a self-review?
- 4 A. Self-assessment, yes.
- 5 Q. As part of a self-assessment, you would assess
- 6 whether you had met the goals that had been set for you
- 7 for the year?
- 8 A. That's correct.
- 9 Q. If you can take a look at CX 3069 in your
- 10 binder.
- 11 This exhibit is included in JX 2 and has been
- 12 admitted in evidence and is not subject to Your Honor's
- 13 in camera ruling.
- 14 A. I'm sorry, which exhibit were you referring to?
- 15 Q. CX 3069. 3069.
- Mr. Camargo, you wrote this email?
- 17 A. I did.
- 18 O. And this attachment?
- 19 A. Yes.
- Q. And you sent it to your boss, Mr. Hildenbrand?
- 21 A. Yes.
- 22 Q. Ms. Wint, can you please put the first page of
- 23 CX 3069 up on the screen.
- 24 Focusing on the last-in-time email, it's dated
- 25 January 17th, 2011, and you wrote: "I corrected this to

- 1 include Oxymorphone being ready to launch on time." Do
- 2 you see that?
- 3 A. I do.
- 4 Q. Can you -- and "oxymorphone" refers to Impax's
- 5 oxymorphone ER product?
- 6 A. Yes.
- 7 Q. The attachment to this email is the year-end
- 8 self-assessment, looking at the goals you had for 2010
- 9 and assessing your performance against those goals?
- 10 A. Yes.
- 11 Q. And you sent this self-assessment to your boss?
- 12 A. Yes.
- Q. If you can turn to CX 3069-002, this is titled,
- 14 "2010 MBOs."
- 15 A. Yes.
- 16 Q. MBOs are your goals for the year?
- 17 A. Yes.
- 18 Q. And "MBO" stands for management by objectives?
- 19 A. Yes.
- 20 Q. And in the table below, on the left, you list
- 21 the objectives for the year?
- 22 A. Yes.
- Q. And then on the right, you list your results in
- 24 accomplishing those objectives?
- 25 A. Yes.

- 1 Q. You also have columns next to -- you have a
- 2 column next to the accomplishments that's labeled "% of
- 3 Salary (Obtained)"?
- 4 A. Yes.
- 5 O. And what does that refer to?
- 6 A. The -- as you can see in the top, there was 10
- 7 percent associated with individual MBOs. That 10
- 8 percent was parsed out by the different objectives
- 9 listed below for a target number on the left side, and
- 10 then on the right side, my self-assessment of how much
- 11 of that I felt I had achieved.
- 12 Q. And to be clear, 10 percent of your salary was
- 13 tied to your achievement of your individual MBOs,
- 14 correct?
- 15 A. A bonus up to 10 percent of my salary was what
- 16 was tied to it, not my actual salary.
- 17 Q. Thank you.
- 18 Can you please turn to the next page,
- 19 CX 3069-003. I'd like to look at the first bullet
- 20 listed on this page. You wrote: "Achieve new product
- 21 launch on the day of ANDA approval without putting
- 22 Company into unnecessary financial or legal risks."
- Do you see that?
- 24 A. Yes.
- 25 Q. And 2 percent of your bonus salary would be

- 1 impacted by your achievement of this goal?
- A. Yes.
- Q. Under "Accomplishments" for that goal, you
- 4 listed oxymorphone as one of four products that were
- 5 approved and intended for launch?
- 6 A. Yes.
- 7 Q. You wrote that oxymorphone was approved and
- 8 ready to launch same day but settled, and then in
- 9 parentheses, "achieved goal"?
- 10 A. Yes.
- 11 Q. You considered this goal to be accomplished with
- 12 respect to oxymorphone ER?
- 13 A. Yes.
- 14 Q. Thank you, Mr. Camargo.
- I have no further questions at this time.
- 16 JUDGE CHAPPELL: Any cross?
- 17 MR. MCINTYRE: Yes.
- 18 JUDGE CHAPPELL: You're on.
- 19 MR. MCINTYRE: Your Honor, may it please the
- 20 Court. My name is Stephen McIntyre with O'Melveny &
- 21 Myers for Impax Laboratories. May I have permission to
- 22 approach the witness to give him a binder?
- JUDGE CHAPPELL: I didn't hear you.
- MR. MCINTYRE: Your Honor, may I approach the
- 25 witness to give him a document binder?

- 1 JUDGE CHAPPELL: Yes, go ahead.
- 2 MR. MCINTYRE: Thank you.
- 3 MS. PEAY: Counsel, can we have a binder?
- 4 MR. MCINTYRE: Sorry about that.
- 5 MS. PEAY: Thank you.
- 6 CROSS EXAMINATION
- 7 BY MR. MCINTYRE:
- 8 Q. Good morning, Mr. Camargo.
- 9 A. Good morning.
- 10 Q. Mr. Camargo, do you have any degrees?
- 11 A. I do.
- 12 Q. What degrees do you have?
- 13 A. I have a bachelor of science degree.
- Q. And where did you earn that degree?
- 15 A. The United States Military Academy, West Point.
- 16 Q. And I believe you went over this earlier, but
- 17 when did you join Impax Laboratories?
- 18 A. In March of 2002.
- 19 Q. And when did you leave the company?
- 20 A. December 2011.
- Q. And have you worked for any other pharmaceutical
- 22 companies?
- 23 A. Yes, I have.
- Q. What companies have you worked for?
- 25 A. I worked for Yale Laboratories; Gensia

- 1 Pharmaceuticals, which was a spinoff from Yale
- 2 Laboratories. And I worked for Synergen, a brief
- 3 biotech startup. And I worked for -- after that Geneva,
- 4 which through merger became Sandoz. I then worked for
- 5 Impax, Ivax, and Teva.
- 6 Q. Altogether, how many years of experience would
- 7 you say you have in the pharmaceutical industry?
- 8 A. At least 27 years.
- 9 Q. I believe Complaint Counsel spoke with you about
- 10 an 18-month planning horizon at Impax. Do you recall
- 11 that?
- 12 A. Yes.
- 13 Q. What determined when a product entered the
- 14 18-month planning horizon?
- 15 A. The first month of forecasted sales falling
- 16 within an 18-month window of the date.
- 17 Q. And who provided that information?
- 18 A. The actual forecast file itself during this time
- 19 frame came from Kevin Sica in the marketing group, but
- 20 the establishment of a target launch date was through a
- 21 different group, and Kevin just passed along the actual
- 22 forecast.
- 23 Q. What group provided the target date you just
- 24 mentioned?
- 25 A. Another person in the marketing group chaired a

- 1 group that included the CEO and a number of vice
- 2 presidents and other people to discuss the product
- 3 portfolio and come up with projected launch dates.
- Q. Were you part of the Marketing Department?
- 5 A. No.
- 6 Q. What department did you belong to?
- 7 A. Operations.
- 8 Q. And was supply chain part of the Operations
- 9 Department?
- 10 A. Yes.
- 11 Q. Was it Impax's practice to begin preparation
- 12 planning for all products within the 18-month planning
- 13 horizon?
- 14 A. That's when we would actually enter the forecast
- 15 and more detailed planning in our ERP system, as well as
- 16 that would trigger the initiation of the product launch
- 17 coordination activities that we were discussing earlier.
- JUDGE CHAPPELL: Sir, I'll need to ask you to
- 19 listen to the question and answer the question. Your
- 20 answer appeared to be a yes, but you never said yes or
- 21 no.
- 22 Would you like her to read the question back?
- THE WITNESS: Yes, please.
- 24 (The record was read as follows:)
- 25 "QUESTION: Was it Impax's practice to begin

- 1 preparation planning for all products within the
- 2 18-month planning horizon?"
- 3 THE WITNESS: Yes.
- 4 BY MR. MCINTYRE:
- 5 Q. Following up on your last answer, Mr. Camargo,
- 6 what happened once a product entered the 18-month
- 7 planning horizon?
- 8 A. Two specific things happened. One, we created
- 9 the necessary master data within the ERP system to
- 10 facilitate the use of that tool for capacity and
- 11 materials planning. And secondly, it would trigger the
- 12 entry of that product onto the Product Launch Checklist
- 13 so that we would then commence coordinating those
- 14 activities that we discussed earlier.
- 15 Q. And did you follow this practice with respect to
- 16 products that were still the subject of active
- 17 litigation?
- 18 A. Yes.
- 19 MS. PEAY: Objection, Your Honor. I don't
- 20 believe there's been a foundation laid that this witness
- 21 is aware of whether the products that he's planning for
- 22 are the subject of active litigation.
- MR. MCINTYRE: If you would like, Your Honor, I
- 24 can ask him further questions to attempt to establish
- 25 the foundation.

- JUDGE CHAPPELL: She would like it, and I think
- 2 it's a good idea. Sustained. Go ahead.
- 3 MS. PEAY: Thank you, Your Honor.
- 4 BY MR. MCINTYRE:
- 5 Q. Mr. Camargo, were you generally aware of whether
- 6 a product that was within the 18-month planning window
- 7 was the subject of litigation?
- 8 A. Yes.
- 9 Q. And I believe you just testified -- but you can
- 10 correct me if I'm wrong -- did Impax follow the
- 11 practices that you just described with respect to the
- 12 18-month launch planning window with respect to products
- 13 that were the subject of active litigation?
- 14 A. Yes.
- Q. Mr. Camargo, did you have any role in selecting
- 16 the forecast date?
- 17 A. No.
- 18 Q. Mr. Camargo, do you recall when oxymorphone ER
- 19 entered the 18-month planning horizon?
- 20 A. I don't recall when it first entered the
- 21 planning horizon.
- Q. I'd like to go ahead and take a look at Exhibit
- 23 RX 181. This should be in the binder --
- JUDGE CHAPPELL: Before you do that, you
- 25 referred to a forecast date. What's a forecast date?

- 1 THE WITNESS: My understanding of the question
- 2 was the date of the forecasted product launch.
- 3 MR. MCINTYRE: Thank you, Your Honor.
- 4 BY MR. MCINTYRE:
- 5 Q. Mr. Camargo, can you please turn to RX 181 in 6 your binder.
- 7 This is an exhibit that appears in JX 2, it is
- 8 admitted in evidence, and it is not subject to in camera
- 9 treatment.
- 10 A. So it's tab 3 then?
- 11 Q. Yes, that's right.
- 12 And, Robert, why don't we go ahead and blow up
- 13 the bottommost email as well as the topmost email.
- Looking at the bottommost email of this chain,
- 15 which actually appears at the top of the screen, are you
- 16 the author of this email?
- 17 A. Yes.
- 18 O. And who is Mr. Smolenski?
- 19 A. Ted Smolenski was a member of our marketing
- 20 group, and he was involved in the -- developing and
- 21 chairing the group that discussed the new product launch
- 22 portfolio.
- 23 Q. Looking at the second paragraph that appears in
- 24 your email, it begins: "We also need to figure out what
- 25 we want to plan for re: Oxycodone."

- 1 Do you see that?
- 2 A. I do.
- 3 Q. I would like to pause here for a moment and look
- 4 at your email that was sent subsequent to this that
- 5 appears at the top of the page, where you write:
- 6 "Sorry, yes, I did mean Oxymorphone."
- 7 Taking the email chain as a whole, do you
- 8 understand that in the bottom paragraph in your June
- 9 4th, 2009, email, you were referring to oxymorphone?
- 10 A. That's correct. I had made an error.
- 11 O. You write in the next sentence in this bottom
- 12 paragraph: "I understand that the odds of launching
- 13 6/10 when the 30-month stay expires may be low, but like
- 14 Tamsulosin, isn't the upside substantial and something
- 15 we may want to plan for?"
- 16 Do you see that?
- 17 A. Yes.
- Q. When you say "6/10," what were you referring to?
- 19 A. The month of June 2010.
- 20 Q. Why did you believe that the odds of launching
- 21 in June 2010 when the 30-month stay expired were low?
- 22 A. Because with other product discussions where we
- 23 had a situation that would lead to a decision for an
- 24 adverse launch, we tended to shy away from such risk.
- 25 So the -- given that this was one of those situations,

- 1 it didn't seem likely to me that we would actually
- 2 launch at that point.
- Q. And so if you thought the odds of launching in
- 4 June 2010 were low, why did you think it was still worth
- 5 planning for?
- 6 A. Because my understanding at that time of the
- 7 potential sales that we could generate from that product
- 8 if we did launch with an exclusive situation, which was
- 9 meaning the only generic on the market, that that could
- 10 be very lucrative for the company and something that we
- 11 may want to prepare for even though the odds that we
- 12 would do it were low.
- 13 JUDGE CHAPPELL: I have a question about the two
- 14 emails on the screen. The one at the top says it was
- 15 sent at 4:27 p.m. on June 4th, 2009, correct?
- 16 THE WITNESS: Yes, sir.
- 17 JUDGE CHAPPELL: And then the one below that
- 18 supposedly corrects something in that top email.
- 19 MR. MCINTYRE: Robert, can you take down the
- 20 two -- blow up --
- JUDGE CHAPPELL: Is that a yes?
- 22 THE WITNESS: Yes, sir.
- 23 JUDGE CHAPPELL: If it's correcting it, the date
- 24 on the one below is also June 4th, 2009, but the time is
- 25 3:30 p.m., which is before the email above it at 4:27

- 1 p.m. How do you explain that?
- THE WITNESS: I can't explain it just by looking
- 3 at the -- what's in front of me, Your Honor.
- 4 MR. MCINTYRE: Robert, can we take --
- 5 THE WITNESS: My guess would be that we were
- 6 working across a three-hour time difference, I being in
- 7 California, Ted being in Philadelphia, and sometimes the
- 8 emails captured the local time, not the -- the time that
- 9 you sent it, so...
- 10 JUDGE CHAPPELL: Can we see the email that he's
- 11 referring to, because he says, "Sorry, I meant oxy" --
- MR. MCINTYRE: Robert, why don't we go ahead and
- 13 blow up the entire chain.
- 14 JUDGE CHAPPELL: So they are in the same email
- 15 chain.
- 16 THE WITNESS: Yes, sir. So you can see what is
- 17 demonstrated here. Chris Mengler's response to me was
- 18 dated before or -- the time is before the time I sent
- 19 it, so that is reflective of the three-hour time
- 20 difference. He actually responded probably two minutes
- 21 later.
- 22 JUDGE CHAPPELL: East versus West Coast? That
- 23 makes sense. Thank you.
- 24 BY MR. MCINTYRE:
- Q. Mr. Camargo, I believe you testified that Impax

- 1 performed process validation for oxymorphone ER. Did I
- 2 get that right?
- 3 A. Yes.
- 4 Q. Are you familiar with the matrix approach to
- 5 process validation?
- 6 A. Yes, I am.
- 7 O. Can you describe what that is?
- 8 A. The default plan for process validations is to
- 9 make three batches of each strength of the product;
- 10 however, depending on the manufacturing process and how
- 11 similar it might be between different strengths, you can
- 12 sometimes abbreviate the process validation by using a
- 13 matrix approach to cover the overall manufacturing
- 14 process in a sufficient manner to meet the FDA's
- 15 requirements. That's where we would do a matrix.
- 16 Q. Are there any advantages associated with using a
- 17 matrix approach?
- 18 A. Sure. You don't have to manufacture as much
- 19 product, so it takes less time, makes it easier to do
- 20 all the necessary testing and analysis on those batches,
- 21 and it reduces the amount of product that you have to
- 22 actually produce during a process validation.
- 23 Q. Are there any cost savings associated with the
- 24 matrix approach?
- 25 A. The cost of the validation batches is going to

- 1 be lower, and, again, you know, if you -- depending on
- 2 whether you need to do a launch inventory build or not,
- 3 you know, you may be able to save some production there.
- 4 Ultimately, you may have to make up for it with launch
- 5 inventory build.
- 6 Q. Do you recall whether Impax used the matrix
- 7 approach when doing process validation for oxymorphone?
- 8 A. Yes, we did.
- 9 Q. And I believe Complaint Counsel asked you
- 10 questions about requesting quota from the DEA. Without
- 11 quota from the DEA, can you buy the API that you need to
- 12 manufacture the product?
- 13 A. No, you cannot.
- 14 Q. And if you can't buy the API, what implications
- 15 does that have if Impax is trying to be launch-ready by
- 16 a target date?
- 17 A. If you cannot buy the API, you cannot start the
- 18 process validation batches, and you're at a standstill.
- 19 Q. And if you can't start the process validation
- 20 batches, is there any way that you can launch the
- 21 product?
- 22 A. No, there is not.
- 23 O. I believe Complaint Counsel reviewed a document
- 24 with you that was CX 3078.
- This document is in evidence and is not subject

- 1 to in camera treatment.
- 2 This was a May 11th, 2010, Product Launch
- 3 Checklist. Do you recall that, Mr. Camargo?
- 4 A. Yes.
- 5 Q. And I believe the checklist targeted a May 28th
- 6 date by which you would -- you anticipated that you
- 7 would complete the launch inventory build. Did I get
- 8 that right?
- 9 A. I generated many of these. I would have to look
- 10 at that specific version to make sure that that's
- 11 accurate.
- 12 Q. Why don't we go ahead and look at task number
- 13 40, and we can extend that over so it includes the
- 14 oxymorphone column. This should be in your binder as
- 15 well. Once again, this is Exhibit CX 3078.
- 16 A. Yes, I can say the date was May 28th at that
- 17 point.
- 18 Q. And do you recall looking at this document with
- 19 Complaint Counsel?
- 20 A. Yes.
- 21 Q. And once again, the date of the cover email is
- 22 May 11th, 2010. Do I have that right?
- 23 A. Yes, I believe so.
- Q. I'd like to take a look at a couple of other
- 25 documents from this period in time. Let's go ahead and

- 1 pull up RX 186. This should be in your binder as well
- 2 if you want to look at a hard-copy version.
- RX 186, this document is in evidence, and it is
- 4 not subject to in camera treatment. This is tab 14 in
- 5 your binder.
- 6 Can you describe the cover email for me?
- 7 A. This is one of the monthly reports I sent to my
- 8 boss that we discussed earlier.
- 9 Q. And can you see the date on which you sent this
- 10 report?
- 11 A. Yes. May 7th, 2010.
- 12 Q. So this was four days prior to the May 11th
- 13 email we just looked at.
- 14 A. Yes.
- 15 Q. Let's go ahead and turn to the attachment, and
- 16 this is RX 186.0003. What is this document,
- 17 Mr. Camargo?
- 18 A. It's a monthly report that I submitted to my
- 19 boss.
- Q. And let's turn the page to RX 186.0004, and,
- 21 Robert, can we go ahead and blow up number 4, under
- 22 "Other Highlights."
- 23 Can you describe what this paragraph is
- 24 communicating?
- 25 A. I'm reporting to Mr. Hildenbrand that the

- 1 oxymorphone ER process validation lots were completed
- 2 and that we're expecting the PV summary report to be
- 3 approved very shortly. At that point, we need
- 4 management decision and direction to proceed with the
- 5 launch inventory build.
- 6 Q. So once the PV summary report was approved, were
- 7 you going to await management decision before proceeding
- 8 with the launch inventory build?
- 9 A. Yes. At that point, we needed management
- 10 approval to proceed with that launch inventory build.
- 11 Q. Also, let's pull up Exhibit CX 2898, and I
- 12 believe that this is one that you also reviewed with
- 13 Complaint Counsel.
- 14 This document is in evidence and it is not
- 15 subject to in camera treatment.
- 16 Mr. Camargo, what is the date of this email?
- 17 A. May 12th, 2010.
- 18 O. And so this is one day after the May 11th
- 19 Product Launch Checklist that we reviewed.
- 20 A. Yes.
- 21 Q. Looking at the bullet points that appear under
- 22 the heading "Oxymorphone," the second one reads, "The PV
- 23 Summary report is expected to be signed off by 5/18 and
- 24 we will not commence the launch inventory build until we
- 25 receive direction to do so from senior management."

- 1 Did I read that correctly?
- 2 A. Yes.
- 3 Q. And so as of May 12th, 2010, was the plan to
- 4 still await direction from senior management before
- 5 beginning the launch inventory build?
- 6 A. Yes, that's correct.
- 7 O. Let's go ahead and take a look at Exhibit
- 8 CX 2904. This should appear in tab 18 in your binder.
- 9 This exhibit is also in evidence, and it is not
- 10 subject to in camera treatment.
- 11 Robert, can we go ahead and blow up the two
- 12 topmost emails.
- 13 Looking at the bottom email that appears there,
- 14 it's from Chuck Hildenbrand. Who was Chuck Hildenbrand
- 15 again?
- 16 A. He was a senior director of operations and he
- 17 was my direct-report.
- 18 Q. He was directing this email to you. He begins,
- 19 "Joe, I don't see the OXM happening in June, let's
- 20 replace it with more MDD."
- 21 Do you see that?
- 22 A. Yes.
- Q. What does "OXM" refer to?
- 24 A. The oxymorphone ER product.
- Q. And what about "MDD"?

- 1 A. It was a product called Midodrine.
- 2 Q. And what do you understand Mr. Hildenbrand to be
- 3 communicating to you here?
- 4 A. He --
- 5 MS. PEAY: I'm sorry, Your Honor. I object.
- 6 Lack of foundation.
- 7 MR. MCINTYRE: Well, Mr. Camargo is the
- 8 recipient of the email, and I was asking for his
- 9 understanding as the recipient of the email.
- 10 MS. PEAY: Your Honor, he's asking for his
- 11 understanding regarding what Mr. Hildenbrand meant, and
- 12 he hasn't laid a foundation that he knows what
- 13 Mr. Hildenbrand meant.
- MR. MCINTYRE: That actually was not the
- 15 question I asked. I asked what his understanding was as
- 16 the recipient of the email.
- JUDGE CHAPPELL: Why don't you just ask him what
- 18 MDD means. If he knows that, he can tell us.
- 19 BY MR. MCINTYRE:
- O. What does "MDD" mean?
- 21 A. It means Midodrine.
- JUDGE CHAPPELL: That way, you don't have to
- 23 worry about his understanding.
- 24 BY MR. MCINTYRE:
- Q. As the recipient of this email, what was

- 1 Mr. Hildenbrand conveying to you?
- 2 A. He had --
- 3 MS. PEAY: Objection -- I'm sorry. Objection.
- 4 Lacks foundation again.
- 5 MR. MCINTYRE: Mr. Camargo can testify as to --
- 6 JUDGE CHAPPELL: Well, this one is more
- 7 problematic than the last version. What he thought it
- 8 meant, he can tell us. What the other man was
- 9 conveying, not so much.
- 10 MR. MCINTYRE: Understood, Your Honor.
- JUDGE CHAPPELL: Rephrase.
- 12 BY MR. MCINTYRE:
- 13 Q. Mr. Camargo, as the recipient of this email,
- 14 what did you think Mr. Hildenbrand meant when he -- with
- 15 this sentence?
- 16 A. I understand that he had reviewed our June
- 17 production plan and that he was telling us that the
- 18 oxymorphone ER product was not likely to be produced
- 19 during June for whatever reason and that we should look
- 20 at replacing that product in our June plan with the
- 21 Midodrine product.
- Q. What was the date of this email?
- 23 A. May 24th, 2010, from him, and May 25th, 2010,
- 24 from me.
- 25 Q. And as you just mentioned, on May 25th, you

- 1 respond to Mr. Hildenbrand, "Okay, I'll look into that.
- 2 I had advised the team that it was unlikely that we
- 3 would make the Oxymorphone, but I kept it in the plan
- 4 just in case."
- 5 First of all, when you say "the team," who are
- 6 you referring to?
- 7 A. Here, I believe I'm referring to the planning
- 8 team that developed this monthly plan.
- 9 Q. And why did you think it was unlikely that you
- 10 would make the oxymorphone as of the date of this email?
- 11 A. For the same reason I testified to earlier, that
- 12 given the situation where it would have been an at-risk
- 13 launch, and we had no history of launching products at
- 14 risk due to the -- you know, the magnitude of the --
- 15 what could happen if we were to lose in the litigation,
- 16 so, you know, I had been given no direction at that
- 17 point in time to actually execute the product launch,
- 18 and it seemed unlikely to me that we would ever do that.
- 19 Q. In fact, did you ever complete the product --
- 20 the launch inventory build?
- 21 A. No, we did not.
- 22 Q. Did you ever receive instruction from senior
- 23 management to begin the launch inventory build?
- A. No, we did not.
- 25 Q. Mr. Camargo, was it unusual for Impax to have to

- 1 discard products or material in inventory?
- 2 A. No. That happened as a matter of course pretty
- 3 much every month.
- 4 Q. Can you estimate about how frequently it
- 5 happened?
- 6 A. Well, we -- I would typically capture what
- 7 happened during a given month, you know, in a monthly
- 8 report to the finance group, as well as these monthly
- 9 reports to Chuck Hildenbrand. There would typically be
- 10 several things that happened during a month, so whether
- 11 they all happened in one week or another week or
- 12 something, that was obviously irregular and not
- 13 something routine.
- 14 JUDGE CHAPPELL: You had told us that you had to
- 15 get DEA approval for the active ingredient in the oxy
- 16 product.
- 17 THE WITNESS: Yes, Your Honor.
- 18 JUDGE CHAPPELL: Then when you destroy that
- 19 product, do you then notify them, or is there any other
- 20 communication with DEA or FDA when it's destroyed --
- 21 THE WITNESS: Yes, Your Honor.
- JUDGE CHAPPELL: -- since it's a controlled
- 23 substance active ingredient, correct?
- 24 THE WITNESS: Yes, sir. It was a finished
- 25 product at that point, and they are both controlled

- 1 substances, and we would have to report to DEA on a
- 2 regular basis the consumption, which would include
- 3 destruction of materials that contained those controlled
- 4 substances.
- 5 JUDGE CHAPPELL: So someone at DEA is supposedly
- 6 keeping track of where this active ingredient is and
- 7 when it's been used and when it's been destroyed.
- 8 THE WITNESS: Yes, Your Honor. We would have to
- 9 report that at least on an annual basis.
- 10 JUDGE CHAPPELL: Go ahead.
- 11 BY MR. MCINTYRE:
- 12 Q. Mr. Camargo, do you recall whether, in June
- 13 2010, Impax had any oxymorphone API on hand that had not
- 14 yet been incorporated into actual oxymorphone ER
- 15 product?
- 16 A. Yes, we did.
- Q. Do you recall what happened with that API?
- 18 A. I believe that API was eventually used. It has
- 19 a longer shelf life than the finished product that was
- 20 manufactured.
- 21 Q. So to your knowledge, the API was not discarded.
- 22 A. That's correct.
- 23 Q. You just mentioned your monthly reports to
- 24 Mr. Hildenbrand. Why don't we go ahead and take a look
- 25 at a monthly -- the Exhibit CX 2905. This is one that

- 1 you also reviewed with Complaint Counsel.
- This document is in evidence and not subject to
- 3 in camera treatment.
- 4 Do you recall seeing this email during --
- 5 A. Yes, I do.
- 6 Q. Okay. Why don't we go ahead and flip to the
- 7 attachment, and we can go to the page CX 2905-003.
- Robert, can we blow up the paragraph that
- 9 appears at the very top of the page.
- 10 Mr. Camargo, once again, what is -- what does it
- 11 mean when you write "Rejects as % of COGS"?
- 12 A. It's referring to the dollar value of what was
- 13 either rejected or something that we expected to end up
- 14 being inventory loss, even if it had not been rejected
- 15 yet, and that dollar value is reflected as a percentage
- 16 of the cost of goods sold for that month.
- 17 Q. And can you tell from this paragraph what the
- 18 dollar value of the rejects were for the month of April
- 19 2010?
- A. Yes. It says April losses were \$1,008,000.
- 21 O. Let's also take a look at Exhibit CX 2896. This
- 22 is also one that I believe you reviewed with Complaint
- 23 Counsel.
- 24 This document is in evidence and it is not
- 25 subject to in camera treatment.

- 1 Do you recall reviewing this document with
- 2 Complaint Counsel?
- 3 A. Yes.
- Q. And let's turn to -- Robert, there's -- we are
- 5 going to get the paragraph that begins at the bottom of
- 6 CX 2896-002 and continues to the top of 003.
- 7 With Complaint Counsel, I believe you reviewed
- 8 the first sentence of this paragraph, which describes
- 9 the \$1.4 million associated with oxymorphone product.
- 10 Do you recall that?
- 11 A. Yes.
- 12 Q. Can you tell from this paragraph, aside from the
- 13 oxymorphone, what the dollar value of Impax's losses
- 14 were for rejected product in June of 2010?
- 15 A. Yes, \$560,000.
- 16 Q. Let's go ahead and turn to Exhibit 29 --
- 17 CX 2922.
- This one is also in evidence and it is not
- 19 subject to in camera treatment.
- 20 For this one, it may be easier to look at a
- 21 paper version of it. That should be in tab 26 of your
- 22 binder.
- 23 Mr. Camargo, do you see your name in the "To"
- 24 field of this email?
- 25 A. Yes.

- 1 Q. And --
- 2 A. Actually, the CC.
- 3 Q. I'm sorry, you're right. It also appears in the 4 CC field.
- 5 And the sender of this email, Willi Huang, who 6 was he?
- 7 A. He was in charge of planning.
- 8 Q. And the subject of this email is, "At Risk
- 9 Inventory report for March 2011." Do you know what the
- 10 at-risk inventory report is?
- 11 A. Yes.
- 12 Q. What is the at-risk inventory report?
- 13 A. It's a report that we provided primarily to the
- 14 cost accounting team in finance to advise them of
- 15 product that was either raw materials or work in process
- 16 or finished goods that for one reason or another we felt
- 17 was unlikely to ultimately be usable.
- 18 Q. And if it was unlikely to be usable, then what
- 19 would happen to it?
- 20 A. Eventually, if that turned out to be accurate,
- 21 that it was unusable, it would eventually be scrapped.
- 22 Q. Let's turn -- Robert, can we turn to the first
- 23 page of the attachment. This is CX 2922-003. Let's go
- 24 ahead and blow up the line at the top that shows the
- 25 column headings.

- 1 Where it says "Description," what does that
- 2 refer to, Mr. Camargo?
- A. Just a description that we put in our ERP system
- 4 for the code number that's in the column to the left.
- 5 Q. And what about the quantity, which appears in
- 6 the column to the right?
- 7 A. That would be the quantity that was considered
- 8 to be at risk from the amount in our inventory.
- 9 Q. And when you say "at risk," what do you mean?
- 10 A. Just as I described earlier, meaning that we
- 11 expected that it would ultimately not be usable for
- 12 commercial purposes for one reason or another.
- 13 Q. And in the next column to the right, "Std Cost,"
- 14 what does that refer to?
- 15 A. It's the standard cost that that product was
- 16 carried at in our ERP system and our financial books.
- Q. And to the right, "Ext. Cost," what does that
- 18 refer to?
- 19 A. The extended cost, which would be the standard
- 20 cost times the quantity.
- 21 Q. Okay. So you arrive at the extended cost by
- 22 multiplying the quantity by the standard cost. Is that
- 23 right?
- 24 A. That's correct.
- Q. Looking two columns over where it says "Risk,"

- 1 what does that refer to?
- 2 A. Just a categorization that we used to
- 3 communicate to finance, whether it was a high, medium,
- 4 or low risk that it would ultimately be rejected.
- 5 Q. And so, for example, looking at the column -- at
- 6 the row number 1 that appears immediately below that, it
- 7 appears that there's an "H" listed in the "Risk" column.
- 8 Do you see that?
- 9 A. Yes, I do.
- 10 Q. And what does the "H" denote?
- 11 A. A high level of risk.
- 12 Q. A high level of risk that the product will have
- 13 to be destroyed?
- 14 A. That's correct.
- 15 Q. And looking at the very top of this page, it
- 16 says, "Raw Materials & Packaging." What does that refer
- 17 to?
- 18 A. We just broke the report -- we sent this
- 19 inventory report to different groups, and this
- 20 particular report was for raw materials and packaging
- 21 components.
- 22 Q. Looking at this page generally, can you
- 23 determine what the total amount of adverse inventory
- 24 value that Impax had for raw materials and packaging as
- 25 of this point in time?

- 1 A. At the bottom of page 003, the Hayward total is 2 a little over \$2 million.
- 3 Q. And what does the "Hayward total" refer to?
- 4 A. We had two main operational areas at this point
- 5 in time. We had a Hayward and we had a Philadelphia
- 6 operation where we did packaging and distribution.
- 7 O. Okay. Let's go ahead and skip to 2922-007.
- 8 Looking at the top of the page, it says, "Bulk Inventory
- 9 & Open Work Orders." Do you know what that refers to?
- 10 A. Yes.
- 11 O. What does that refer to?
- 12 A. Bulk inventory would be product in the form of
- 13 tablets or capsules that we had manufactured but not yet
- 14 packaged, so they would typically be in fiber drums.
- 15 And open work orders would be work in process where we
- 16 had started working on them but had not yet finished
- 17 them through manufacturing.
- 18 Q. Looking at this page, it appears that there are
- 19 several rows that are highlighted in yellow. Do you
- 20 know what the yellow highlighting denotes?
- 21 A. Yes. The yellow highlighting indicated that it
- 22 was new to that -- that month.
- Q. So these are materials that were added to the
- 24 list in this particular month. Is that right?
- 25 A. Yes.

- 1 MS. PEAY: Objection, Your Honor. This is --
- 2 seems to be beyond the scope of the direct. I don't see
- 3 how this is connected to oxymorphone ER from my direct
- 4 examination.
- 5 MR. MCINTYRE: Well, Complaint Counsel elicited
- 6 testimony concerning the destruction of oxymorphone
- 7 quantities, and actually in a minute we will see that
- 8 the oxymorphone is listed here. I would like to provide
- 9 some context for understanding when and under what
- 10 circumstances Impax has to write off product.
- 11 JUDGE CHAPPELL: All right. I agree, it is
- 12 within the scope, and another point is we have this
- 13 problem occasionally when a witness is called who is on
- 14 both witness lists, and if he wants to take this witness
- 15 as his own at this time, he's allowed to go beyond the
- 16 scope of direct in this limited circumstance.
- MS. PEAY: I understand, Your Honor. My
- 18 understanding is that Mr. Camargo is not on Respondent's
- 19 witness list.
- 20 MR. MCINTYRE: That's correct.
- JUDGE CHAPPELL: All right. Well, I overruled
- 22 the objection in this case.
- MS. PEAY: Okay, thank you.
- MR. MCINTYRE: Thank you, Your Honor.
- 25 BY MR. MCINTYRE:

- 1 Q. Mr. Camargo, I believe you just testified that
- 2 the yellow highlighted products here represent bulk
- 3 inventory and open work orders that were added to this
- 4 list in this particular month. Did I state that
- 5 correctly?
- 6 A. That's correct.
- 7 O. And can you determine the risk that's associated
- 8 with these products? I'm sorry, let me rephrase that.
- 9 Can you determine from this document the risk
- 10 that this inventory would have to ultimately be
- 11 discarded?
- 12 A. Yes. In the "Risk" column, they're all
- 13 indicated as "H," meaning high.
- 14 Q. Can you determine the total amount of new bulk
- 15 inventory and work orders that were added to the list
- 16 for this particular month?
- 17 A. For that month, it was approximately \$618,000.
- 18 THE COURT: You said earlier that the stock was
- 19 in fiber drums. What kind of fiber?
- THE WITNESS: Fiberboard containers basically,
- 21 cylindrical containers made out of fiberboard, and we
- 22 would have that product in tablet or capsule form
- 23 double-bagged inside those containers. Those were
- 24 facilitated -- that's how we packaged it to ship it to
- 25 our Philadelphia packaging operation.

- JUDGE CHAPPELL: So the product would be within
- 2 plastic bags inside the fiber drum?
- 3 THE WITNESS: Correct.
- 4 BY MR. MCINTYRE:
- 5 Q. Let's go ahead and turn to CX 2922-009, and at
- 6 the top of this page, it reads, "Finished Goods in
- 7 Distribution." What does that mean, Mr. Camargo?
- 8 A. These were products that were completely
- 9 packaged and ready for sale.
- 10 Q. How is this distinguished from bulk inventory?
- 11 A. The bulk inventory would be product that was
- 12 still awaiting packaging. It was still in loose tablet
- 13 and capsule form as it came out of manufacturing.
- 14 Q. Okay. And looking at the first few rows here,
- 15 it lists oxymorphone HCL. Do you see that?
- 16 A. I do.
- 17 Q. And for -- in rows number 1, 2, and 3, it says
- 18 britestock. What does britestock refer to?
- 19 A. Britestock product is packaged in the final
- 20 container, but the labeling has not yet been applied to
- 21 it, and, therefore, the full packaging is not yet
- 22 completed.
- Q. And so at this point in time, the oxymorphone
- 24 product was at risk of having to be discarded?
- 25 A. I'm sorry. Can you repeat the question?

- 1 Q. I'm sorry.
- 2 At this point in time, was the oxymorphone
- 3 product at risk of having to be discarded?
- 4 A. Yes.
- 5 Q. Let's look further down the page. Robert, can
- 6 you pull up rows 10 through 21.
- 7 Mr. Camargo, what is Digoxin?
- 8 A. Digoxin was just another product that we had
- 9 prepared for launch.
- 10 Q. I'm not going to ask you to do the math
- 11 precisely, but looking at the "Extended Cost" column,
- 12 can you give a guesstimate, a rough estimate, as to the
- 13 total value of the Digoxin product that was listed here?
- MS. PEAY: Your Honor, I object that this
- 15 question is beyond the scope of direct.
- 16 JUDGE CHAPPELL: Right. Based on this
- 17 objection, I'm sustaining it until you can lay a
- 18 foundation and bring this within the scope of the
- 19 questions he was asked by opposing counsel.
- 20 MR. MCINTYRE: Understood, Your Honor. I can
- 21 withdraw that question.
- MS. PEAY: Thank you, Your Honor.
- BY MR. MCINTYRE:
- Q. Mr. Camargo, can you determine the total amount
- 25 of new -- I'm sorry, the total value of new listings of

- 1 finished goods in distribution for this month?
- A. From this report, the total for that month was
- 3 1.16 million.
- 4 Q. Okay. Given your 27 years of experience in the
- 5 pharmaceutical industry, would you say that it is
- 6 unusual to have to discard inventory?
- 7 A. No, it's not, unfortunately.
- 8 Q. I'm going to switch gears a bit. Let's go ahead
- 9 and pull up CX 3069, and this is another exhibit that
- 10 you reviewed with Complaint Counsel.
- 11 This exhibit is in evidence and it is not
- 12 subject to in camera treatment.
- 13 Do you recall reviewing this document with
- 14 Complaint Counsel?
- 15 A. Yes.
- 16 Q. Let's turn to -003, and can we go ahead and blow
- 17 up this.
- I believe you reviewed the line with Complaint
- 19 Counsel where it says, "Oxymorphone: approved and ready
- 20 to launch same day but settled (achieved goal)."
- 21 Do you recall that, Mr. Camargo?
- 22 A. Yes.
- Q. When you said "approved and ready to launch,"
- 24 what did you mean?
- 25 A. That we were -- well, approved means that the

- 1 process validation report was signed off and those
- 2 batches were all ready to be released should management
- 3 have given us the go-ahead to do it; and that we were
- 4 also ready to execute the launch inventory build that we
- 5 were ultimately told not to execute.
- 6 Q. And when you just -- you said "those batches" a
- 7 minute ago, were you referring to the process validation
- 8 batches?
- 9 A. Yes.
- 10 Q. And, Mr. Camargo, you reviewed some documents
- 11 earlier, some of your monthly reports to -- that you
- 12 would send to your boss, Mr. Hildenbrand. Do you recall
- 13 those?
- 14 A. Yes.
- 15 Q. And do you recall that there was a line in those
- 16 reports that would say "Percentage" -- I'm sorry,
- 17 "Rejects as a % of COGS"?
- 18 A. Yes.
- 19 Q. And was that a goal that you attempted to
- 20 achieve generally in the operations division?
- 21 A. Yes.
- 22 Q. Looking at your self-evaluation here in CX 3069,
- 23 there's a column that says "Objectives," and I'm looking
- 24 at -002. What does "Objectives" refer to?
- 25 A. The objectives were the goals that we set for

- 1 that year.
- Q. Does the goal of achieving a -- of limiting
- 3 rejects to a certain percentage of COGS, does that goal
- 4 appear here?
- 5 A. Yes.
- 6 Q. It does? Can you point me to it?
- 7 A. In the second block on the left side. Oh, I'm
- 8 sorry, I can't --
- 9 Q. Does that --
- 10 A. No, I'm sorry.
- 11 Q. I'm sorry, go ahead.
- 12 A. I was looking at the screen and couldn't read it
- 13 all. Can you expand it?
- 14 Q. Yeah. Can we go ahead and --
- 15 A. I can't see the whole thing right now.
- 16 Q. Where it says "COGS at 50% or less of net
- 17 sales."
- 18 A. No, it's -- the COGS at 50% or less of net sales
- 19 has nothing to do with rejects.
- 20 Q. Okay. Do you see anything here concerning
- 21 rejects as a percentage of COGS?
- 22 A. Not with what I can see on this screen right
- 23 now.
- Q. You can go ahead and look at the full document,
- 25 if you like. This is at tab 24 of your binder.

- 1 A. Tab 24. (Document review.) No, it's not on
- 2 this particular year's objectives statement.
- Q. Mr. Camargo, do you have any responsibility for
- 4 deciding ultimately whether to launch a product?
- 5 A. Do I have any responsibility for what? Excuse 6 me?
- 7 Q. I can rephrase that.
- 8 Mr. Camargo, were you responsible for deciding
- 9 whether to launch a product?
- 10 A. No, I was not.
- 11 Q. Who was responsible for that?
- 12 A. Ultimately, Larry Hsu would be responsible.
- Q. And Larry Hsu was the CEO at this time?
- 14 A. Yes.
- 15 Q. Mr. Camargo, do you have any knowledge of when
- 16 the settlement negotiations with Endo began?
- 17 A. No, I do not.
- Q. When did you first hear about the settlement
- 19 with Endo?
- 20 A. To the best of my recollection, I heard about it
- 21 when the settlement was announced.
- 22 Q. So you were not part of the team that negotiated
- 23 the settlement?
- 24 A. No, I was not.
- 25 MR. MCINTYRE: Your Honor, may I briefly confer

- 1 with counsel?
- 2 JUDGE CHAPPELL: Go ahead.
- 3 (Counsel conferring.)
- 4 MR. MCINTYRE: Thank you, Mr. Camargo. No
- 5 further questions at this time.
- 6 JUDGE CHAPPELL: Any redirect?
- 7 MS. PEAY: Your Honor, may I have a moment to
- 8 confer with counsel?
- 9 JUDGE CHAPPELL: Go ahead.
- 10 (Counsel conferring.)
- 11 MS. PEAY: Your Honor, I will have some
- 12 redirect.
- 13 JUDGE CHAPPELL: Okay.
- 14 REDIRECT EXAMINATION
- 15 BY MS. PEAY:
- 16 Q. Hello again, Mr. Camargo.
- 17 A. Hello.
- 18 Q. Can you turn to the exhibit RX 181 that counsel
- 19 for Respondent -- it's in Respondent's binder. I think
- 20 it is tab 3.
- 21 A. Okay.
- Q. And, Mr. Camargo, counsel for Respondent
- 23 discussed this exhibit, RX 181, with you earlier today,
- 24 just now?
- 25 A. Yes.

- 1 Q. And focusing on the first email that you sent at
- 2 the bottom of the page, counsel asked you questions
- 3 about your -- what you wrote here, where you said, "I
- 4 understand that the odds of launching 6/10 when the
- 5 30-month stay expires may be low..."
- 6 A. Yes.
- 7 O. Do you recall that?
- 8 And, Mr. Camargo, your understanding of -- that
- 9 the odds of launching the oxymorphone product in June
- 10 2010 as being low was based upon your general experience
- 11 at Impax and in the industry, correct?
- 12 A. In part, yes.
- 13 Q. It was not based upon an assessment of the
- 14 oxymorphone ER product, in particular?
- 15 A. There was discussion in other meetings that I
- 16 participated in where that particular product and its
- 17 particular likelihood was logically discussed in. I
- 18 don't have any specific recollection of that discussion.
- 19 Clearly, from my experience, there may have been
- 20 discussions about that product. I don't recall the
- 21 details of them.
- 22 Q. So, sitting here today, you don't know -- you
- 23 cannot recall of any other basis for your understanding
- 24 that the odds of launching in June 2010 as being low,
- 25 other than your general experience.

- 1 A. I can't recall any specifics. It is very
- 2 possible that there were other discussions, but I don't
- 3 recall any specifics.
- 4 Q. But you don't know of any?
- 5 A. No, I do not.
- 6 MS. PEAY: No further questions, Mr. Camargo.
- 7 Thank you, Your Honor.
- 8 JUDGE CHAPPELL: Anything further?
- 9 MR. MCINTYRE: None for us, Your Honor.
- 10 JUDGE CHAPPELL: Thank you. You may stand down.
- 11 We are going to take a short break and come back
- 12 and start with our next witness. We will reconvene at
- 13 12:05. We are in recess.
- 14 (A brief recess was taken.)
- JUDGE CHAPPELL: We are back on the record.
- 16 Next witness.
- 17 MR. LOUGHLIN: Thank you, Your Honor. Complaint
- 18 Counsel calls Dr. John Geltosky. My colleague Mr. Dan
- 19 Butrymowicz will conduct the examination.
- 20 Whereupon--
- JOHN E. GELTOSKY, Ph.D.
- 22 a witness, called for examination, having been first
- 23 duly sworn, was examined and testified as follows:
- 24 DIRECT EXAMINATION
- 25 MR. BUTRYMOWICZ: Good afternoon, Your Honor.

- 1 May it please the Court.
- 2 JUDGE CHAPPELL: Go ahead.
- 3 BY MR. BUTRYMOWICZ:
- 4 Q. I'm Dan Butrymowicz on behalf of Complaint
- 5 Counsel.
- 6 Good afternoon, Dr. Geltosky.
- 7 A. Good afternoon.
- 8 Q. How are you?
- 9 A. Doing fine.
- 10 Q. Would you please introduce yourself by stating
- 11 your full name.
- 12 A. I am John Edward Geltosky.
- 13 Q. Would you please also briefly describe your
- 14 professional background.
- 15 A. I have a Ph.D. in biochemistry from Cal Tech.
- 16 I've worked in the pharmaceutical biotech industry for
- 17 roughly 37 years. I've worked both at large
- 18 pharmaceutical companies, small pharmaceutical
- 19 companies. I've also been involved in technology
- 20 transfer, and I am currently a consultant to biotech,
- 21 too, in licensing and business development.
- 22 Q. Thank you.
- Dr. Geltosky, I've placed a binder next to your
- 24 seat that contains several exhibits that we may
- 25 reference during the direct examination. There is no

- 1 need to refer to it right now. There is also a bottle
- 2 of water next to your seat if you need it.
- 3 Before we discuss your professional experience,
- 4 let me first review the issue that you were asked to
- 5 address in this case. What did the FTC ask you to
- 6 assess in this matter?
- 7 A. They asked me to provide an opinion regarding
- 8 the due diligence, the negotiation history, and the
- 9 terms of the draft -- of the license -- development
- 10 co-promotion agreement between Impax and Endo, and I was
- 11 to weigh in on the consistency with what I saw there
- 12 with the practices and norms of the pharmaceutical
- 13 industry when they consider and enter into an agreement
- 14 of this sort.
- 15 Q. Without saying what your opinion is, have you
- 16 formed an opinion on that issue?
- 17 A. Yes, I have.
- 18 Q. Before we get to that opinion, I would like to
- 19 ask you about your professional experience, your
- 20 education, and your training. You said a moment ago
- 21 that your background is in pharmaceutical business
- 22 development. Generally speaking, what is pharmaceutical
- 23 business development?
- 24 A. Well, inside of all pharmaceutical companies,
- 25 large and small, there exists a function called business

- 1 development, and it is a goal of the business
- 2 development agreement basically to fill the pipeline,
- 3 where necessary, with projects or technologies that come
- 4 from outside the four walls of that -- of the particular
- 5 company.
- 6 A little known fact is that roughly half the
- 7 drugs that a given pharmaceutical company markets come
- 8 from outside those four walls of their company. So we
- 9 have in business development the window on the rest of
- 10 the world to go find assets that are strategic to fill
- 11 the pipeline.
- 12 Q. You used the term "asset." What do you mean by
- 13 that term?
- 14 A. Typically, in this case, I'm referring to drugs
- 15 in development. In some cases we look at market --
- 16 already marketed drugs that the originator wanted to
- 17 license out, to get rid of, but typically it's drugs in
- 18 development.
- 19 Q. When you introduced yourself, you mentioned that
- 20 you had worked for major pharmaceutical companies in
- 21 business development. Which companies were those?
- 22 A. In business development, I worked -- well, I
- 23 actually did business development work at Johnson &
- 24 Johnson, I did business development work at SmithKline
- 25 Beecham, and I also did similar activity at

- 1 Bristol-Myers Squibb.
- O. Let's take those one at a time. Let me ask you
- 3 first about your work at Bristol-Myers Squibb. What was
- 4 your title at Bristol-Myers Squibb?
- 5 A. I was the vice president of external science,
- 6 technology, and licensing.
- 7 Q. And what were your responsibilities as vice
- 8 president of external science, technology, and
- 9 licensing?
- 10 A. Myself and my group of 15 professionals were
- 11 responsible for finding those assets on the outside that
- 12 fit into the therapeutic areas that were of interest to
- 13 Bristol at that time. So it was our responsibility to
- 14 find those molecules, find those assets, evaluate them,
- 15 do technical evaluation, and work with our Legal
- 16 Department and our Commercial Department to basically
- 17 develop a commercial model for the -- for the asset,
- 18 which would then lead to negotiations.
- 19 Q. And how long were you vice president of external
- 20 science, technology, and licensing at Bristol-Myers
- 21 Squibb?
- 22 A. Five-plus years.
- 23 O. You also mentioned SmithKline Beecham. What was
- 24 your title at SmithKline Beecham?
- 25 A. I was vice president of scientific licensing in

- 1 the Worldwide Business Development Department.
- Q. What were your responsibilities as vice
- 3 president of scientific licensing and director of
- 4 scientific licensing?
- 5 A. Very similar to what I had at Bristol.
- 6 Q. How long were you in that role?
- 7 A. Five years.
- 8 Q. In pharmaceutical business development, what is
- 9 in-licensing versus out-licensing?
- 10 A. Well, in-licensing, you're a net buyer. That's
- 11 what we typically -- what we were responsible for. So
- 12 we would -- we were basically looking to acquire assets
- 13 on the outside. So we were buyers in that role.
- 14 JUDGE CHAPPELL: You used the word "licensing"
- 15 there. Are you talking about patents, patented drugs?
- 16 THE WITNESS: Typically, yes.
- JUDGE CHAPPELL: Did you have anything to do
- 18 with patents?
- 19 THE WITNESS: I, myself, am not a patent
- 20 attorney. I always -- it was always important for us in
- 21 evaluating a technology or a potential acquisition to
- 22 understand -- have an opinion of the intellectual
- 23 property bolstering that particular asset.
- 24 JUDGE CHAPPELL: Did you do your job based on
- 25 assumptions or guidance that was given to you by the

- 1 Legal Department?
- THE WITNESS: I'm sorry, I didn't hear you
- 3 properly.
- 4 JUDGE CHAPPELL: Did you do your job based on
- 5 assumptions of patent validity that was provided to you?
- 6 THE WITNESS: Yes. I mean, the patent -- our
- 7 Patent Department would weigh in, and we would sometimes
- 8 debate it, sometimes go a little bit back and forth, but
- 9 we would rely on the Patent Department to provide that
- 10 opinion for us.
- MR. BUTRYMOWICZ: Thank you, Your Honor.
- 12 BY MR. BUTRYMOWICZ:
- 13 Q. I also want to clarify a little bit about
- 14 licensing as you describe it. When you use the term
- 15 "in-licensing," are you referring only to licensing
- 16 development agreements?
- 17 A. No. I used that sort of euphemistically. I
- 18 mean, that can also -- it includes co-development type
- 19 of agreements, co-promotion agreements, but it's easy
- 20 for me just to think about it as licensing, because that
- 21 is the underlying basis of all these other activities.
- 22 Q. So when we discuss pharmaceutical licensing
- 23 agreements, you generally understand that to mean any
- 24 type of pharmaceutical development deal?
- 25 A. Yes, all-encompassing.

- Q. In your experience at Bristol-Myers Squibb and
- 2 SmithKline Beecham, were you responsible for reviewing
- 3 potential pharmaceutical development opportunities?
- 4 A. Yes.
- Q. Were you involved in selecting opportunities to 6 pursue?
- 7 A. Yes.
- 8 Q. Were you responsible for performing due
- 9 diligence on those opportunities?
- 10 A. Yes.
- 11 O. Were you involved in negotiations for
- 12 pharmaceutical development agreements?
- 13 A. I participated in a team format. Typically it's
- 14 a fairly large -- well, not a large team, but there's a
- 15 number of people that are involved in the negotiation.
- 16 Q. Does your more than ten years of experience at
- 17 SmithKline Beecham and Bristol-Myers Squibb relate to
- 18 the opinions that you intend to give in this case?
- 19 A. Yes.
- 20 O. How does it relate?
- 21 A. Because during that period I participated in
- 22 numerous -- which I'm sure we will get into -- numerous
- 23 licensing and evaluation opportunities. So you -- one
- 24 becomes -- and I certainly became -- very immersed in
- 25 all the moving parts that go into a business development

- 1 licensing agreement. So, perforce, that has informed my 2 opinion on this subject.
- Q. In addition to your experience as an executive
- 4 at Bristol-Myers Squibb and SmithKline Beecham, you also
- 5 mentioned that you're currently a consultant. Is that
- 6 correct?
- 7 A. That is correct.
- 8 Q. Where are you currently employed?
- 9 A. JEG & Associates.
- 10 Q. What is JEG & Associates?
- 11 A. Well, basically, it is an LLC that I formed to
- 12 provide business development/licensing consulting
- 13 practice -- consulting advice to typically a small -- to
- 14 small biotech companies as they consider finding a
- 15 partner for their asset.
- 16 Q. What are your responsibilities at JEG &
- 17 Associates?
- 18 A. So working with a typical client, I will work
- 19 with them in terms of formulating an overall strategy
- 20 that relates to their R&D activities. So, in essence,
- 21 what I advise these people on are the kinds of
- 22 experiments, the kinds of data, the kinds of knowledge
- 23 that must be brought to bear to entice a potential
- 24 partner.
- 25 In this business, partnerships are -- rule

- 1 everything. A small biotech company is great at
- 2 originating and discovering brand new drugs, but they
- 3 need large pharmaceutical companies to help them with
- 4 development and commercialization. So I enable them to
- 5 entice potential partners for their assets.
- I help them draft their presentations,
- 7 nonconfidential. I help them put together their
- 8 confidential data packages. I basically am the
- 9 ombudsman for that whole process on behalf of my client,
- 10 and I participate in negotiations and give advice as
- 11 needed.
- 12 Q. So you mentioned that in your role at
- 13 Bristol-Myers Squibb and SmithKline Beecham you were
- 14 involved primarily in analyzing things, and I think you
- 15 said you were a net buyer. In your role at JEG &
- 16 Associates, are you primarily a net buyer or a net
- 17 seller?
- 18 A. I'm a net seller.
- 19 Q. And how does that differ from being a net buyer
- 20 or in-licenser?
- 21 A. Well, when you're a net seller, you're
- 22 essentially a salesman, so you're trying to entice a
- 23 particular -- a -- an interest in forming partnerships.
- 24 So it's -- the rules of the game are basically
- 25 identical, and what allows me to be a good seller, I

- 1 think, or to help my companies sell is I know from a
- 2 buyer standpoint what a buyer, a potential buyer, is
- 3 looking for. So it's just the same dynamic, just
- 4 different sides of the street, if you will.
- 5 Q. Before JEG & Associates, where were you
- 6 employed?
- 7 A. Prior to that -- to JEG & Associates, I was
- 8 with -- I was employed at Arizona State University.
- 9 Q. What was your title there at Arizona State?
- 10 A. I was senior vice president of technology
- 11 transfer for the life science activities there.
- 12 Q. What were your responsibilities in that role?
- 13 A. Very similar, actually, to what I'm doing with
- 14 biotechs, and I should say that I still am a consultant
- 15 to Arizona State. So I would work with the professors,
- 16 the inventors at the university, putting together what I
- 17 would hope -- what we hoped to be attractive packages,
- 18 again, to entice a licensor, you know, for this
- 19 technology, whether it be a small biotech, a large
- 20 pharmaceutical company, or a venture.
- 21 Q. Did your work at Arizona State focus on products
- 22 in any particular stage of development?
- 23 A. They were all very -- because of the university
- 24 environment, very early-stage technologies.
- 25 Q. In your role at JEG & Associates and Arizona

- 1 State University, did you interact with other
- 2 pharmaceutical companies?
- 3 A. Certainly.
- 4 Q. Roughly how many would you say you interacted
- 5 with during those roles?
- 6 A. Just referring to the consulting -- to the JEG
- 7 and the Arizona State? Dozens, many dozens.
- 8 Q. Did you get any -- any experience seeing how
- 9 those companies approached pharmaceutical development?
- 10 A. Certainly.
- 11 O. Does your experience at JEG & Associates and at
- 12 Arizona State University inform any of the opinions you
- 13 intend to give in this case?
- 14 A. Yes, they do.
- 15 Q. How do they inform them?
- 16 A. Well, again, this is just another sort of subset
- 17 of the licensing business development arena, and this is
- 18 particularly -- the -- the areas that you've just drawn
- 19 my attention to are particularly applicable to this
- 20 because the asset in question here for the -- in the
- 21 agreement between Endo and Impax is defined as very
- 22 early stage.
- 23 Q. Do you currently hold any other positions, in
- 24 addition to your employment at JEG & Associates?
- 25 A. Yeah, I'm the chairman of the Product

- 1 Development Review Committee for CPRIT, and CPRIT stands
- 2 for Cancer Prevention Research Institute in Texas.
- 3 O. What is CPRIT?
- 4 A. CPRIT is a funding agency put forth or put out
- 5 by the State of Texas. When Rick Perry was the Governor
- 6 of Texas, he was able to entice the taxpayers to
- 7 basically invest \$3 billion over a ten-year period, so
- 8 that's \$300 million a year, to invest in cancer
- 9 research, both basic research in the universities in
- 10 Texas and also, where I come into play here, small
- 11 companies that are in -- you know, that are resident in
- 12 the State of Texas or who are willing to move to Texas
- 13 that are advancing novel therapies and diagnostics
- 14 related to cancer.
- 15 Q. And what are your responsibilities as the chair
- 16 of the Commercial Review Council for CPRIT?
- 17 A. So of that \$300 million, about a third of that
- 18 is allocated to commercial aspects, which I am in charge
- 19 of. So in my role, I have -- these are -- they are
- 20 called grants, but, in fact, they're really business
- 21 plans that we review. So I have roughly three to four
- 22 dozen professionals that I use, that I can call on, to
- 23 provide review.
- These are peer-reviewed grants, if you will, and
- 25 so I'm responsible for organizing all of those

- 1 functions, to assign people, and basically to come up
- 2 ultimately with investment decisions that we are willing
- 3 to fund, that we think have good technical sense and
- 4 good business sense.
- 5 Q. Does your work as the chair of the Commercial
- 6 Review Council for CPRIT relate to any of your opinions
- 7 in this case?
- 8 A. Ah, yes. Even though we're not talking about an
- 9 oncology drug here, we're talking about a Parkinson's
- 10 drug, these are all very early-stage companies. So the
- 11 dynamic, the meat and potatoes that goes into business
- 12 plans, the analyses are very similar to what one would
- 13 do in analyzing this particular project.
- 14 Q. Dr. Geltosky, are you on the board of directors
- 15 of any pharmaceutical companies?
- 16 A. Yes.
- 17 Q. Which companies?
- 18 A. So I'm on the board of a company in LaJolla
- 19 called Sophiris, and I'm also on the board of a company
- 20 in Vancouver, Canada, called Sitka.
- Q. In addition to the experience you've just
- 22 described in pharmaceutical business development, do you
- 23 also have experience working in pharmaceutical research
- 24 and development?
- 25 A. Yes. That's how I started my career.

- Q. And can you briefly describe that experience?
- 2 A. Well, I started my career in the laboratory at
- 3 Dupont in 1980, and that was more -- that was really a
- 4 diagnostics rather than therapeutics, but the mind-set
- 5 that one applies in developing new products and
- 6 diagnostics have a lot of overlap with pharmaceutical
- 7 products. And, in fact, it's a very heavily regulated
- 8 industry, just as therapeutics are, so that informs a
- 9 lot of your activities in terms of how you do your job.
- 10 So when I switched over to the pharmaceutical
- 11 area, I was basically involved in both research and
- 12 development. I was involved in discovering new
- 13 therapies across a variety of therapeutic areas. I
- 14 collaborated closely with research scientists at Scripps
- 15 and other institutions, Rockefeller being another
- 16 example, and I also did a lot of what I would call
- 17 straight development work.
- 18 So for a couple of years I was in charge of
- 19 developing stable formulations and doing analytical
- 20 methods development for a molecule called erythropoietin
- 21 that Johnson & Johnson was selling through their
- 22 relationship with Amgen.
- 23 O. Approximately how long did you work in
- 24 pharmaceutical research and development?
- 25 A. Approximately 15 years.

- 1 Q. And were you at Johnson & Johnson for the 2 majority of that time?
- 3 A. Ten of those years, yes, roughly ten.
- 4 Q. Does your 15 years of experience in research and
- 5 development relate to any of the opinions you intend to
- 6 give in this case?
- 7 A. Certainly.
- 8 O. How?
- 9 A. Well, in doing research, one is using a --
- 10 doing -- applying the scientific rigor to the analysis
- 11 of the asset, at least on the technical front, and so
- 12 the science that one does in the laboratory, you bring
- 13 that to bear to analyze other projects that somebody
- 14 else might be doing, but you'll -- you review the data
- 15 with the same degree of rigor that you would be
- 16 reviewing your own data and of your group.
- 17 Q. Dr. Geltosky, all told, approximately how many
- 18 years of experience do you have working in the
- 19 pharmaceutical industry?
- 20 A. In toto, roughly 37.
- 21 Q. In your 37 years in the pharmaceutical industry,
- 22 approximately how many pharmaceutical development
- 23 opportunities have you been involved in?
- 24 A. Well, starting from just searching, you know,
- 25 for projects that -- for assets that we would be --

- 1 SmithKline or Johnson & Johnson or BristolMeyers would
- 2 be interested in, thousands, many thousands.
- 3 Q. And of those thousands, how many have you
- 4 pursued to consider a potential development deal?
- 5 A. Well, back in 2006 -- I'll just take that
- 6 snapshot -- when I was at BMS, a part of my job was to
- 7 provide some metrics to management. So in that year,
- 8 3 -- we reviewed -- myself and my group reviewed 3000
- 9 potential asset acquisitions or licensing, however you
- 10 want to define it. So of those 3000, we were serious
- 11 enough, we were interested enough then to sign a CDA, a
- 12 confidentiality agreement, on 300 of those.
- 13 We don't take the CDAs lightly because you put
- 14 yourself at risk that you are now obligated to hold
- 15 things in confidence for usually five to seven years, so
- 16 that's an important sort of barrier for us. Of those
- 17 300, 30 of them wound up being interesting enough to
- 18 pursue further. And in that further pursuit, that
- 19 involved intense technical due diligence, which meant
- 20 going to visit the company with an army of scientists,
- 21 usually taking a couple of days to go through all the
- 22 data that the company has available to them, that they
- 23 presented to us in summary form, so we were just
- 24 confirming that what they were telling us was, in fact,
- 25 true.

- 2 again, are very serious undertakings -- we did three
- 3 deals in that particular year. So there was a
- 4 logarithmic funneling.
- 5 Q. And that year, 2006, those three deals you
- 6 described, was that representative of most years that
- 7 you worked at Bristol-Myers Squibb or SmithKline
- 8 Beecham?
- 9 A. Yeah. It was not an extraordinary year. I just
- 10 happened to be taking account.
- 11 Q. Outside of your formal job responsibilities,
- 12 what other experience do you have that's relevant to
- 13 your opinion in this case?
- 14 A. Well, like I said, I have been in the industry
- 15 for 37 years, and I have immersed myself in that
- 16 industry. So especially in licensing business
- 17 development for that last 15 years where I have been
- 18 active, I've participated very actively in a number of
- 19 industry-sponsored events. I was a speaker at a number
- 20 of events, international events. I was on a panel where
- 21 the topics we're discussing basically, best practices in
- 22 licensing/business development. So I became -- I became
- 23 a popular speaker. People wanted to invite me to come
- 24 to do these presentations.
- 25 So I continue, even though I'm not working for

- 1 anybody else, per se, I don't have an employer, I still
- 2 spend a lot of time just keeping abreast of what's going
- 3 on in the industry, and there are two ways that I do --
- 4 actually, there's a number of ways I do it, but most
- 5 significantly, I rely on a daily bulletin that gets
- 6 published that everybody in the industry knows about,
- 7 it's called BioWorld, and BioWorld is sort of the trade
- 8 sheet of the pharmaceutical biotech industry, but it
- 9 focuses on business development deals.
- There's a second source, similar in nature, not
- 11 quite as extensive, called FierceBiotech. Where they
- 12 came up with that name, I don't know. I read journals.
- 13 I still subscribe to Science, where there is a lot of
- 14 work in Science describing drug discovery. I read the
- 15 Wall Street Journal, the New York Times, and The
- 16 Financial Times with my eye on what's going on in the
- 17 pharmaceutical industry. So I maintain an awareness of
- 18 the trade.
- 19 Q. What academic degrees do you hold?
- 20 A. I have a Ph.D. in biochem from Cal Tech. I have
- 21 completed a postdoctoral fellowship at Scripps Clinic in
- 22 LaJolla. And I hold a bachelor's degree, magna cum
- 23 laude, from University of Memphis.
- 24 MR. BUTRYMOWICZ: Your Honor, at this point, I
- 25 tender Dr. Geltosky as an expert in pharmaceutical

- 1 business development agreements. I submit that he's
- 2 qualified by reason of his 37 years of professional
- 3 experience in the industry, his education, his training,
- 4 to provide expert testimony on whether the overall
- 5 strategic fit, negotiation history, due diligence
- 6 efforts, and terms of the development and co-promotion
- 7 agreement between Endo and Impax are consistent with the
- 8 usual and expected practice in the pharmaceutical
- 9 industry.
- 10 JUDGE CHAPPELL: Are you finished?
- 11 MR. BUTRYMOWICZ: Yes.
- 12 JUDGE CHAPPELL: That might be the longest one
- 13 I've ever heard.
- MR. BUTRYMOWICZ: I apologize, Your Honor.
- 15 JUDGE CHAPPELL: Any objection?
- MS. FABISH: No objection.
- JUDGE CHAPPELL: I can't hear you unless you
- 18 stand up.
- 19 MS. FABISH: No objection, Your Honor.
- 20 JUDGE CHAPPELL: You don't want to start a bad
- 21 habit there. Any opinions that meet the proper legal
- 22 standards will be considered.
- 23 MR. BUTRYMOWICZ: Thank you, Your Honor.
- 24 BY MR. BUTRYMOWICZ:
- 25 Q. Dr. Geltosky, now that we have reviewed your

- 1 qualifications as an expert in the area of
- 2 pharmaceutical development agreements, let's get to your
- 3 actual opinions in this case.
- 4 In your opinion, was the overall strategic fit,
- 5 negotiation history, due diligence efforts, and terms
- 6 for the development and co-promotion agreement between
- 7 Endo and Impax consistent with the usual and expected
- 8 practice in the pharmaceutical industry?
- 9 A. No.
- 10 Q. Do you hold that opinion with a degree of
- 11 certainty that's reasonable in your professional field?
- 12 A. Yes.
- Q. In a moment, I'd like to go through the
- 14 different parts of that opinion in more detail, but
- 15 first, in general terms, can you describe how you came
- 16 to arrive at your opinions in this case?
- 17 A. Well, I was provided a whole raft of documents
- 18 to review from the FTC that had quite a bit of
- 19 information in those. I analyzed those through the lens
- 20 of my experience of reviewing and participating and
- 21 creating licensing/business development/co-promotion
- 22 types of agreements. So I used that experience that
- 23 informed my opinion of reviewing and analyzing the
- 24 information provided by the Federal Trade Commission.
- 25 Q. Before turning to anything specific about this

- 1 agreement, I'd like to get an understanding of the
- 2 process that pharmaceutical companies, in your
- 3 experience, typically follow for development agreements.
- 4 Can you explain in very general terms what a
- 5 pharmaceutical development agreement is?
- 6 A. Well, basically, a -- it's a -- it's a legal
- 7 contract between two companies who have agreed to work
- 8 together to develop and possibly then commercialize an
- 9 asset that is owned by one of the parties. There's a
- 10 lot of meat in these agreements. They cover -- there is
- 11 a roadmap of how this is going to -- how the project is
- 12 going to be developed, a sense of timing of when events
- 13 are going to occur.
- 14 There's a -- there's a description of how the
- 15 product is going to be commercialized, who has
- 16 responsibility. Actually, a licensing agreement spells
- 17 out in great detail who is responsible for all the
- 18 myriad activities that are -- that are necessary to
- 19 advance a compound all the way through to
- 20 commercialization.
- There's a description of the committees, the
- 22 decision-making process, and last, but not least, there
- 23 is information about the compensation, the quid pro quo,
- 24 how the money flows between the two parties.
- 25 Q. From a commercial perspective, are there

- 1 different forms that a pharmaceutical development
- 2 agreement could take?
- 3 A. Yes. There -- as we've touched on before,
- 4 there's licensing agreements, there's co-development
- 5 agreements, there's co-promotion/co-development
- 6 agreements.
- 7 O. In terms of what you've described as the meat of
- 8 the agreements, are there any significant differences
- 9 between those different commercial forms?
- 10 A. They -- there are some differences. There are
- 11 more similarities than there are differences, and the
- 12 differences, say, in a co-promotion agreement is how the
- 13 finances get cut and how the -- it's basically, in
- 14 essence, a profit-sharing agreement, so it comes down to
- 15 if Party A is putting in \$100, Party B is putting in
- 16 \$50, the eventual profit split, in simple terms, is
- 17 judged on those contributions, those investments.
- 18 Licensing agreements don't do that. They just
- 19 talk about up-fronts, milestones, royalties, and there's
- 20 often another mechanism by which development is funded,
- 21 but it's not necessarily a co-development agreement.
- Q. Over the course of your career, were the
- 23 development agreements that you worked on limited to
- 24 products in a specific stage of development?
- 25 A. No, they ran the gamut, from preclinical through

- 1 to -- practically to registration, to -- to sending in
- 2 the NDA.
- Q. In your experience, do pharmaceutical companies
- 4 follow the same general process for evaluating and
- 5 entering development deals?
- 6 A. Yes.
- 7 Q. On a very high level for now, what is that
- 8 process?
- 9 A. Well, you find it. You do the technical
- 10 evaluation. You do the intellectual property
- 11 evaluation. You develop a commercial model. Then
- 12 you -- if you're still interested, then there's
- 13 diligence all along the way, and if you're still
- 14 interested, you go into negotiations.
- 15 Q. In your experience, does this process vary based
- 16 on the size of the company?
- 17 A. No.
- 18 O. And why do pharmaceutical companies follow this
- 19 type of process before entering a business development
- 20 deal?
- 21 A. It's a very logical process, and basically what
- 22 one is trying to do, whether it's a small company or a
- 23 big company, is mitigate risk. And so you go through
- 24 this set of analyses to understand the risks, to measure
- 25 the risks, to quantitate the risks, and put a dollar

- 1 value on that risk. So it's a way -- you just -- you
- 2 just manage risk.
- Q. I'd now like to ask you more in-depth about your
- 4 opinions, starting with your opinion about the
- 5 negotiations for the Endo-Impax development and
- 6 co-promotion agreement.
- 7 At a high level, what's the basis for your
- 8 opinion that the negotiations for this agreement were
- 9 not consistent with the usual practice in the
- 10 pharmaceutical industry?
- 11 A. Well, there were two -- two components.
- 12 The first was it happened -- the speed at which the
- 13 agreement was finalized was remarkable, very fast, a
- 14 very short period.
- 15 The second thing that I found odd and very much
- 16 out of place was that the focus of the agreement changed
- 17 literally at the 11th hour. That was an unprecedented
- 18 change in focus in these kinds of agreements.
- 19 Q. Let's take those one at a time. Turning first
- 20 to your opinion that the negotiations were concluded
- 21 very quickly, unusually quickly, what is your basis for
- 22 that opinion?
- 23 A. It's based on my experience. I've never seen
- 24 anything happen that fast.
- 25 Q. In your 37 years of experience in the

- 1 pharmaceutical industry, how long does it typically take
- 2 to complete an early-stage pharmaceutical development
- 3 deal from start to finish?
- 4 A. From the very start when you find the asset,
- 5 when it crosses your desk or you find it, and to
- 6 completing the agreement, the average is 12 months.
- 7 O. Are there circumstances where you've seen a
- 8 development deal completed in less than 12 months?
- 9 A. I believe -- yeah, I can't draw a precise
- 10 recollection, but I am aware of, stumbling around, maybe
- 11 something within nine months being done, not that we
- 12 participated in, but I have heard through the industry,
- 13 talking to other people, maybe less -- a little bit less
- 14 than a year.
- 15 Q. Are there any circumstances, based on your
- 16 experience, that might drive a deal to be completed in
- 17 less than the usual time?
- 18 A. If there's competition for an asset, that could
- 19 increase the speed.
- 20 Q. Did the development agreement between Endo and
- 21 Impax involve any competition for the asset?
- 22 A. Not that I -- not that I could see.
- 23 O. How long did the negotiations between Endo and
- 24 Impax for the co-development and promotion agreement
- 25 take?

- 1 A. Well, for the eventual product, IPX-203, they
- 2 negotiated -- once that was divulged to Endo, they
- 3 completed that agreement in four days.
- 4 O. And putting aside the focus on the second
- 5 product, which we'll discuss in a moment, how long did
- 6 the overall negotiations for any form of the development
- 7 and co-promotion agreement take?
- 8 A. I can't do the math. Here they started talking
- 9 about another compound, another molecule, in May,
- 10 mid-May, and they concluded the agreement on June 8th, I
- 11 believe. So I think it was less than a month.
- 12 Q. In your experience, how unusual is it that
- 13 negotiations for a development agreement would be
- 14 concluded, from start to finish, in less than a month?
- 15 A. Extremely unusual.
- 16 Q. Based on your review of Endo's documents, did
- 17 Endo have a documented approach to how it negotiated
- 18 business development agreements?
- 19 A. Yes.
- 20 Q. I'd like to ask you to turn to CX 2784, which is
- 21 in your binder.
- 22 Your Honor, CX 2784 is admitted in evidence,
- 23 it's on JX 2, and it is not subject to Your Honor's in
- 24 camera order.
- 25 And, Dr. Geltosky, I would specifically like to

- 1 direct your attention to CX 2784-20.
- 2 A. Yes, uh-huh.
- 3 Q. Do you recognize this document?
- 4 A. Yes.
- 5 Q. Did you review it in preparing your report?
- 6 A. Yes.
- 7 O. Have you seen similar documents at
- 8 pharmaceutical companies that you've worked with?
- 9 A. Yes.
- 10 JUDGE CHAPPELL: Hold on a second.
- 11 (Discussion off the record.)
- 12 JUDGE CHAPPELL: Go ahead.
- 13 BY MR. BUTRYMOWICZ:
- Q. Based on your experience in the industry, what
- 15 does CX 2784 represent?
- 16 A. The -- this whole document?
- 17 Q. Yes.
- 18 A. It's a roadmap of how one acquires an asset from
- 19 the outside.
- Q. I'd like to direct your attention specifically
- 21 to CX 2784-54. Based on your experience in the
- 22 industry, what does CX 2784-54 describe?
- 23 A. This is a version of a roadmap of how they -- of
- 24 how Endo went about their normal business practices of
- 25 evaluating and doing due diligence, going to various

- 1 committees for discussion and approval, all the way
- 2 through to a close of the agreement.
- Q. Is Endo's description of the pharmaceutical
- 4 development deal negotiation process in this document
- 5 consistent with your own experience in the industry?
- 6 A. Yes.
- 7 O. At the bottom of this page, CX 2784-54, it
- 8 states, "~ 6 months 1 year from initial evaluation to
- 9 deal close." Do you see that?
- 10 A. Yes.
- 11 Q. Is that timeline consistent with your experience
- 12 working on pharmaceutical business development deals?
- 13 A. Yes.
- 14 Q. Dr. Geltosky, I'd like to change focus just
- 15 slightly and ask you about something you mentioned a
- 16 moment ago, which is the change in focus between two
- 17 products during these negotiations.
- 18 Based on your 37 years of experience in the
- 19 industry, why do you say it was unusual that the
- 20 negotiations changed focus from one product to another?
- 21 A. Well, in this case, the originator, Impax, had
- 22 disclosed or had -- well, the two parties were very
- 23 obviously discussing an asset called IPX-066. They were
- 24 discussing that asset as demonstrated in various emails.
- 25 There was no other discussion. It was IPX-066 for a

- 1 couple weeks. So then, all of a sudden, it changed.
- Q. And what did it change to?
- 3 A. It went to something -- the topic -- the focus
- 4 became something called IPX-203.
- 5 Q. And, Dr. Geltosky, the Court has ordered some of
- 6 the technical and scientific information about IPX-203
- 7 in camera, and so we can't discuss it in a public
- 8 session. I intend to request an in camera session
- 9 toward the end of this examination to get into those
- 10 details, and I want you to be careful in this public
- 11 session not to provide any scientific or technical
- 12 details about IPX-203.
- 13 With that in mind, from a practical standpoint,
- 14 how was IPX-203 different from IPX-066?
- 15 A. It was at the very earliest stages of the drug
- 16 development process, I'll call it discovery, and the
- 17 lead molecule had not yet been identified.
- 18 Q. You said that IPX-203 was at the earliest stage
- 19 of the development process. At the time that Endo and
- 20 Impax were negotiating this agreement, where was IPX-066
- 21 in the development process?
- 22 A. It was preparing to enter Phase III, the last
- 23 stage of the drug development process.
- Q. From a practical standpoint, based on your
- 25 experience, what does it mean for a product to be in

- 1 Phase III of clinical development?
- A. It means that a lot of risk has been taken out.
- 3 It's been -- successfully gone through the endpoints of
- 4 the preclinical, has an IND, has gone through Phase I,
- 5 has gone through Phase II, they have defined a dose, and
- 6 now they're preparing to do what are generally
- 7 considered to be confirmation studies, but they are
- 8 large, expensive studies in Phase III. That is the last
- 9 step in the process.
- 10 Q. Based on your 37 years of experience in the
- 11 pharmaceutical industry, is it unusual for companies to
- 12 change from discussing a development deal for a product
- 13 in Stage III of development to a product in discovery
- 14 stage?
- 15 A. Well, in my 37 years, I personally have never
- 16 experienced that, nor have I ever heard any of my peers
- 17 at other companies say that it happened to them.
- 18 Q. Based on your experience, how would a
- 19 pharmaceutical company like Endo typically react if its
- 20 negotiating partner changed the product being discussed
- 21 from a Stage III clinical product to an early-stage
- 22 product over the course of the negotiations?
- 23 A. Well, I would have called time-out and said I
- 24 needed to spend some time to do a proper valuation on
- 25 this newly defined asset.

- 1 Q. And why would you have done that?
- 2 A. Because it's different -- it's a different
- 3 chemical. I can't get into the details here. So one
- 4 would want to do technical due diligence. Certainly one
- 5 would want to do intellectual property due diligence,
- 6 because a new asset is being defined. One would want to
- 7 do other types of technical due diligence. And very
- 8 importantly, one would have wanted to redo the entire
- 9 commercial analysis of the asset.
- 10 Q. And why would a company want to do all those
- 11 things?
- 12 A. Because it's a brand new -- I'm sorry. It's a
- 13 brand new project. It's fresh territory. Throw
- 14 everything way. Start a new analysis.
- 15 Q. Moving on from the negotiations, I'd like to
- 16 briefly discuss your opinion that the Endo-Impax
- 17 co-development deal was not a strategic fit with Endo's
- 18 business. Can you start by explaining what the concept
- 19 of "strategic fit" means in the pharmaceutical industry?
- 20 A. A strategic fit is that you have other
- 21 activities going on, let's say, that this would be
- 22 complementary to. So in a commercial sense, if you were
- 23 in a given therapeutic area and selling a particular
- 24 product there -- and let's say it's just one product --
- 25 you would like to have a second product in that

- 1 therapeutic area, that the salespeople would be
- 2 detailing to the same physician audience, and that
- 3 basically cuts your sales cost in half.
- 4 O. What are the bases for your conclusion that the
- 5 Endo-Impax development deal was not a strategic fit with
- 6 Endo's business?
- 7 A. Kind of twofold. One is, in my review of the
- 8 information, the internal presentations and so forth at
- 9 Endo that I saw, there was no mention of Parkinson's
- 10 disease being an area of interest. There were plenty of
- 11 other therapeutic areas, plenty of other diseases that
- 12 they were interested in. So I didn't see any interest
- 13 in Parkinson's.
- 14 Secondly, they also talked about only being
- 15 interested in late-stage assets, things that were near
- 16 term, say within a couple years of being on the market,
- 17 near-term revenue generators. Those would be late-stage
- 18 products.
- 19 IPX-203 is something that's still in the
- 20 laboratory. In fact, at the time the agreement was
- 21 signed, they weren't even in the laboratory. So that
- 22 didn't seem to have a strategic fit either.
- 23 Q. Thank you, Dr. Geltosky.
- I'd like to change topics now and ask you about
- 25 your opinion that the terms of the development and

- 1 co-promotion agreement were not consistent with the
- 2 usual practice in the pharmaceutical industry.
- In your report you identify a number of unusual
- 4 terms in the agreement, but I'd like to focus on the
- 5 financial structure of the deal. Based on your 37 years
- 6 of experience in the industry, is the structure of the
- 7 Impax-Endo development and co-promotion deal consistent
- 8 with what you would expect for a development deal of an
- 9 early-stage pharmaceutical product?
- 10 A. No, because it's very front-loaded.
- 0. What do you mean by "front-loaded"?
- 12 A. A lot of money is put at risk at the very
- 13 earliest stages of the program. At the start of the
- 14 program, the \$10 million up front. The second milestone
- 15 is the same amount, \$10 million, and then they diminish
- 16 over the course of time. That's the exact opposite of
- 17 the way agreements like this are structured.
- 18 They -- the milestone payments actually, in
- 19 every agreement that I've ever seen, increase as risk is
- 20 taken out of the program. Value is created. The
- 21 originator then is sort of rewarded with a larger
- 22 milestone payment reflecting that increased value by
- 23 taking risk out. So backload versus frontload.
- 24 Q. You mentioned both the up-front payments and
- 25 milestone payments, and I'd like to take those one at a

- 1 time. In your opinion, was the \$10 million up-front
- 2 payment in this agreement unusually large?
- 3 A. For an early-stage compound of this sort, in
- 4 this therapeutic area, with the eventual fairly small
- 5 market it was going to be addressing, it was very large.
- 6 Q. And why is it unusual to have a payment this
- 7 large for, as you said, an early-stage product?
- 8 A. You're basically -- in this particular case,
- 9 they were putting 25 percent down of a -- at least 25
- 10 percent, maybe even more down on the up-front payment of
- 11 the total precommercialization milestones. That's a
- 12 very high percentage, especially for a molecule of this 13 sort.
- 14 Q. Based on your experience, what percentage would
- 15 you expect the up-front payment to be for an early-stage
- 16 development deal like this?
- 17 A. I would say somewhere between 5 -- of the total
- 18 deal, 5 to 10 percent.
- 19 Q. Dr. Geltosky, isn't \$10 million a very small
- 20 amount of money for a company like Endo?
- 21 A. No.
- Q. Why do you say that?
- 23 A. \$10 million is \$10 million. A company like Endo
- 24 has a fairly small treasury from which to draw, so \$10
- 25 million is -- actually, it's a meaningful amount for any

- 1 pharmaceutical company, large or small.
- When I would bring in products where, you know,
- 3 there was in the neighborhood of \$10 million or so being
- 4 put at risk, I really had to justify that. That comes
- 5 out of somebody's budget.
- The important thing to consider is besides the
- 7 \$10 million, that can buy you a lot of things, but in
- 8 this case, it's an opportunity cost. So a company like
- 9 Endo -- and any company -- you want to be able to put
- 10 all your chips down where you think you're going to get
- 11 a payback. So that -- that informs my -- my discussion
- 12 on that.
- 13 Q. I'd also like to ask you about the milestone
- 14 payments. I believe you mentioned that, in your
- 15 experience, it's unusual for them to decrease over the
- 16 course of the agreement, but let me first ask you, what
- 17 is a contingency milestone payment?
- 18 A. Some event has to be successfully accomplished;
- 19 that is, in this particular case, the first milestone
- 20 was completion -- successful completion of a Phase II
- 21 clinical trial.
- 22 Q. Why is it unusual that the milestone payments
- 23 would decrease as the agreement progressed?
- 24 A. That's why I say, I don't understand why they
- 25 decreased in this case, because in every agreement that

- 1 I've ever seen, they go in the reverse direction. They
- 2 increase because value is being created during the
- 3 course of the program. Less risk is taken. Risk is
- 4 taken out. It's more likely that the project will
- 5 eventually see the light of day.
- 6 Q. And, Dr. Geltosky, I just want to make sure that
- 7 I understand your testimony correctly. You earlier
- 8 mentioned that there was an opportunity cost associated
- 9 with this \$10 million payment. Can you explain a little
- 10 bit more what you meant by that?
- 11 A. Well, if you're spending \$10 million on this,
- 12 then you're not spending \$10 million on that, and so
- 13 they could apply that \$10 million in their case any
- 14 number of ways. They could look to acquire another
- 15 project. They can look to beef up their clinical trials
- 16 or accelerate their clinical development of other
- 17 projects that may be further along. They could invest
- 18 that money in enhancing their sales force or increase
- 19 their marketing budget, all of which would be aimed at
- 20 increasing their -- eventually increasing their
- 21 revenues. So there are any number of ways they could
- 22 spend that money or invest it.
- 23 O. Thank you.
- 24 Given the risks inherent in IPX-203 as an
- 25 early-stage product, how would you have expected, based

- 1 on your experience, companies like Endo and Impax to
- 2 structure a deal like this?
- 3 A. Well, I certainly would have -- for a deal like
- 4 this, I would certainly have seen a more backloaded
- 5 agreement if you're just looking at the traditional
- 6 up-fronts and milestones and so forth. But a better way
- 7 that -- of approaching this -- and this is a methodology
- 8 that was familiar to both companies -- is to do an
- 9 option agreement.
- 10 So in this case, looking at the two parties,
- 11 Endo could have paid Impax a small amount of money to
- 12 tell Impax, please do not shop this to anybody else.
- 13 We're interested, but we're only interested if certain
- 14 things are done in the laboratory or even in the clinic
- 15 before we're willing to commit to larger dollars.
- 16 Q. In your experience, why do pharmaceutical
- 17 companies use option agreements like you just described?
- 18 A. It's a great risk mitigator. You're not putting
- 19 a lot of money at risk until you see something that
- 20 convinces you it has a higher probability of success.
- 21 Q. In one of your answers a few minutes ago, you
- 22 used the term "backloaded." Can you explain what you
- 23 mean by that term?
- 24 A. "Backloaded" means that the payments, the
- 25 success payments, the contingency payments increase in

- 1 amount.
- Q. So the opposite of frontloaded?
- 3 A. It's the opposite of frontloaded, yes.
- 4 Q. Moving on from the terms of the agreements, I'd
- 5 like to turn now to your opinion that Endo's due
- 6 diligence for the Impax development and co-promotion
- 7 agreement was not consistent with the usual process in
- 8 the industry.
- 9 At a very high level, what is the basis for that
- 10 opinion?
- 11 A. Well, they really did not appear, during that
- 12 four-day period, to look at anything of a technical
- 13 nature that would have convinced them that this project
- 14 wasn't that risky and it had a decent chance of success.
- 15 So a review of technical information for -- for
- 16 starters.
- 17 Q. Before we get into detail on that, can you
- 18 please explain generally what "due diligence" means in
- 19 the pharmaceutical industry?
- 20 A. Well, basically, due diligence, as I referred to
- 21 it before, is that when you're doing full technical due
- 22 diligence, which would be at this point in this project,
- 23 you would look at all the data that the other company
- 24 had developed that would lead one to believe that the
- 25 compound is going to be both safe and efficacious and

- 1 that it had a good chance of development success over
- 2 the given period of time that the company said it would
- 3 be on the market, and, importantly, that it would have a
- 4 competitive label, because in this particular case, this
- 5 drug was going to face lots of competition.
- 6 Q. Is there a standard process that pharmaceutical
- 7 companies follow to conduct diligence for a development
- 8 agreement?
- 9 A. Yes. You look at all the data that are
- 10 available, and you bring in the experts in the
- 11 particular area to render a judgment on the quality of
- 12 the data.
- 13 Q. Based on your review of the record, did Endo
- 14 follow the standard process for conducting diligence?
- 15 A. No.
- 16 Q. Dr. Geltosky, if I could direct you to -- I
- 17 apologize, I think my question was unclear. Not
- 18 referring to the process Endo followed for this
- 19 agreement, but referring to Endo's general practices,
- 20 did -- did your review of the record reveal that Endo
- 21 had any general process for the way it conducted
- 22 diligence?
- 23 A. Yes. Looking at some of their other work, yes,
- 24 they had a -- they had a process.
- 25 Q. And directing your attention back to CX 2784,

- 1 which we discussed earlier and it's in your binder, in
- 2 particular, CX 2784-50 --
- 3 A. Yes.
- 4 Q. -- based on your experience in the industry,
- 5 what does this page represent?
- 6 A. Again, it's another process map for how one
- 7 evaluates an opportunity all the way through to a
- 8 transaction, and it has some timings on it, which is all
- 9 very reasonable.
- 10 Q. Is this due diligence process that Endo
- 11 describes here consistent with your own experience in
- 12 the pharmaceutical industry?
- 13 A. Yes.
- Q. In your experience, how long does it typically
- 15 take to do due diligence for a development agreement?
- 16 A. It takes roughly -- to actually conduct the full
- 17 due diligence, write the reports, have the discussions,
- 18 around four months, three to four months.
- 19 Q. How long did Endo spend on due diligence for
- 20 this agreement with Impax?
- 21 A. I'm sorry, which compound?
- 22 Q. I'm sorry. How long did Endo spend on due
- 23 diligence in total for this agreement with Impax?
- 24 A. Well, for 203, they had four days to do their
- 25 evaluation, both technical and commercial and

- 1 intellectual property.
- Q. And you just mentioned intellectual property
- 3 analysis. I'd like to turn now to that part of
- 4 diligence. Generally speaking, what is an intellectual
- 5 property analysis?
- 6 A. Basically one is evaluating the quality of the
- 7 patents, and, again, as we've referred to before, I'm
- 8 not a patent attorney, but you are really looking at two
- 9 things. The first thing and I think the most important
- 10 thing is the freedom to operate, the FTO, and basically
- 11 that's a review of the available patent literature to
- 12 see if, by exploiting this, your particular technology,
- 13 are you going to be infringing somebody else's patent.
- 14 JUDGE CHAPPELL: Are you explaining an analysis
- 15 that you actually do or someone else does?
- 16 THE WITNESS: Well, I'm relying on somebody else
- 17 doing it, but I know what they're doing. I
- 18 understand --
- 19 JUDGE CHAPPELL: Why don't we stick to what he
- 20 does rather than what someone else does.
- MR. BUTRYMOWICZ: Yes, Your Honor.
- 22 BY MR. BUTRYMOWICZ:
- 23 O. Dr. Geltosky, if I could turn now to your
- 24 opinion that Endo's financial analysis of the IPX-203
- 25 opportunity was not consistent with the usual practice

- 1 in the industry. Let me start by asking, in your
- 2 experience, what is a financial analysis conducted as
- 3 part of a pharmaceutical development deal?
- 4 A. Well, a financial analysis basically tells you
- 5 what you think -- based on some assumptions and
- 6 calculations what you think that particular asset is
- 7 going to be worth, and that informs you on a couple of
- 8 levels --
- JUDGE CHAPPELL: Again, is this an analysis that
- 10 you do yourself?
- 11 THE WITNESS: Ah, I do.
- 12 JUDGE CHAPPELL: All right, go ahead.
- 13 THE WITNESS: I participate in that analysis,
- 14 yes. I understand all the moving parts.
- 15 JUDGE CHAPPELL: Go ahead.
- 16 THE WITNESS: All right. So basically to do
- 17 this analysis to -- to inform you of whether or not you
- 18 want to do the deal at the end of the day, can I make
- 19 enough money off of this. And secondly, relatedly,
- 20 what -- what sort of milestones and so forth should I be
- 21 paying to make this, you know, a -- you know, for --
- 22 during my negotiations, because you definitely do not
- 23 want to be overpaying.
- 24 BY MR. BUTRYMOWICZ:
- 25 Q. What is the output of a financial analysis in

- 1 your experience?
- 2 A. The output is so-called net present value or an 3 NPV.
- 4 O. And what is an NPV?
- 5 A. NPV is a financial tool that most businesses
- 6 use, but the pharmaceutical industry relies on it very
- 7 heavily. It looks at the cash flows discounted over
- 8 time at a certain discount rate, a rate of return,
- 9 versus the original investment that's put into it. So
- 10 typically an NPV, if it's positive, that -- it means
- 11 it's worthy of an investment.
- 12 O. At a high level, what is the basis for your
- 13 opinion that Endo's financial analysis of the IPX-203
- 14 opportunity was not consistent with the usual practice
- 15 in the industry?
- 16 A. Well, for one thing, they -- to go back to the
- 17 NPV, there should be another initial put in front of the
- 18 NPV, and it's an "r," a little "r," that means
- 19 risk-adjusted NPV. An NPV, without taking into
- 20 consideration the risk of failure in development, is
- 21 really a number that doesn't have a lot of power, a lot
- 22 of worth to it.
- 23 So in my review of the information provided to
- 24 me, I did not see that Endo took risk at all into
- 25 consideration, which is very important, especially for

- 1 an early-stage asset, and especially, too, for this
- 2 particular molecule because it's going to face terrific
- 3 competition if it ever did get to the market, so that,
- 4 perforce, more risk is attached to it.
- 5 The second area of -- where I found that they
- 6 were remiss in their financial analysis is the
- 7 assumptions that they used to put into their model.
- 8 Q. Let's take those one at a time. Let me first
- 9 ask about your opinion that the financial analysis did
- 10 not adequately take into account the risks of IPX-203.
- 11 How do financial evaluations typically account for risk
- 12 and uncertainty?
- 13 A. Well, at every stage of development, there is
- 14 a -- every year -- well, there's a sort of
- 15 industry-accepted success rate for -- going from
- 16 preclinical to Phase I, Phase I to Phase II, Phase II to
- 17 Phase III, Phase III to the NDA, NDA to approval.
- 18 There's risk, so those events don't always happen.
- 19 And so there are statistics, usually on an
- 20 annual basis, and people rely on those factors to come
- 21 up with an overall risk for the particular project.
- 22 They -- you don't just generally rely on the particular
- 23 published, say, risk of going from Phase II to Phase
- 24 III. You look at and analyze the particular asset, see
- 25 what endpoint it's going to have to meet, and judge

- 1 whether or not it has a higher or lower probability of
- 2 success versus what is quoted in the industry.
- And everybody relies on those industry numbers,
- 4 and those are basically multiplied by the cash flow, so
- 5 if it has a risk -- a probability of success of 70
- 6 percent, you take the cash flow at that particular
- 7 point -- and early in the process, it's a negative
- 8 number -- so you multiply that by 0.7 to say that that's
- 9 the money that is...
- 10 Q. Is it standard practice to include a risk
- 11 adjustment in a financial analysis of a pharmaceutical
- 12 development agreement?
- 13 A. Yes.
- 14 Q. Did Endo take any steps to account for the risks
- 15 of IPX-203 in its financial analysis?
- 16 A. Not that -- not that I could see in the
- 17 documents.
- 18 O. Was this failure to account for the risks of
- 19 IPX-203 consistent with industry standards?
- 20 A. Well, no. Everybody does do an rNPV eventually.
- 21 O. What effect would this failure to account for
- 22 the risks of IPX-203 have on the valuation?
- 23 A. You're flying blind.
- 24 Q. I'd like to ask you about the second opinion you
- 25 mentioned, that many of the assumptions that Endo used

- 1 for its financial analysis of IPX-203 were improper.
- 2 And, again, we're still in a public session, so let me
- 3 ask you first, generally, without getting into any
- 4 specific assumptions that Endo used, what is your basis
- 5 for the opinion that some of the assumptions were
- 6 improper?
- 7 A. They were relying on work that was done for the
- 8 predecessor molecule, so-called IPX-066. They had
- 9 commissioned a market research firm to come up with
- 10 basically a model, and so they relied on those numbers
- 11 for that particular asset to come up with a valuation
- 12 for the new asset, and I thought that was inappropriate.
- 13 Q. In your experience, where do pharmaceutical
- 14 companies normally get the assumptions that they use in
- 15 these financial analyses?
- 16 A. Doing -- there's a lot that goes into it, but
- 17 the real driver is market research. They either do it
- 18 themselves or they commission somebody to do it.
- 19 Q. I'd like to ask you in a little more detail --
- 20 well, let me first ask, did Endo do any market research
- 21 on IPX-203?
- 22 A. No.
- 23 O. You mentioned that it was -- that it was unusual
- 24 for Endo to use the assumptions that it had formulated
- 25 for IPX-066 in its analysis of IPX-203. Can you explain

- 1 in a little more detail -- again, without getting into
- 2 specifics about the chemical nature of IPX-203 -- why
- 3 that was so unusual?
- 4 A. Well, a couple things. One is they were at
- 5 vastly different stages of development, so the timelines
- 6 and so forth were really skewed. A lot would happen in
- 7 the marketplace between the time that IPX-066 was
- 8 approved and on the market versus when IPX-203 would be
- 9 on the market, so that -- that shift in the timeline
- 10 would have a big effect on the quality of that market
- 11 research.
- 12 And I don't know if we want to get into other
- 13 details about --
- 14 Q. We will get into details --
- 15 A. Okay.
- 16 Q. -- but let's hold off for now.
- 17 A. Sure.
- 18 MR. BUTRYMOWICZ: Your Honor, at this point I
- 19 would like to question Dr. Geltosky about areas that are
- 20 subject to Your Honor's in camera order. I, therefore,
- 21 request, Your Honor, a brief in camera session and to
- 22 clear the courtroom.
- 23 JUDGE CHAPPELL: Okay. At this time, we are
- 24 going to be discussing in camera information. Those of
- 25 you not subject to the protective order in this case

- 1 need to leave the courtroom. The Bailiff will let you
- 2 know when you may re-enter the courtroom.
- 3 MR. BUTRYMOWICZ: Thank you, Your Honor.
- 4 JUDGE CHAPPELL: I will need to -- I will need
- 5 the attorneys at counsel table to look behind you and
- 6 verify the people sitting behind you are subject to the
- 7 protective order.
- 8 MR. LOUGHLIN: We're fine on our side, Your
- 9 Honor.
- 10 MS. FABISH: I'm sure -- I -- yes, Your Honor.
- 11 (Whereupon, the proceedings continued in
- 12 in camera session.)
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(The following proceedings were held in
 2 in camera session.)
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          (Public session.)
          JUDGE CHAPPELL: Law Man, you can let the public
 3 know that we are going into public session, but we're
 4 breaking for lunch.
          All right, I need the parties' assessment. Do
 6 we need to cut lunch shorter or does the full hour work
 7 for today? You can confer.
          MR. HASSI: Your Honor, I think it's a close
 9 call whether we go past 5:30. I don't think from our
10 collective estimates that we would go past 6:00 if we
11 still took an hour lunch, but --
          JUDGE CHAPPELL: All right, we will take 55
13 minutes. We will reconvene at 3:00 p.m. We're in
14 recess.
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         (Whereupon, at 2:05 p.m., a lunch recess was
16 taken.)
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- 1 AFTERNOON SESSION
- 2 (3:05 p.m.)
- JUDGE CHAPPELL: Okay, we are back on the
- 4 record. Go ahead.
- 5 MS. FABISH: Thank you, Your Honor.
- 6 May I approach the witness to offer him a
- 7 document binder?
- 8 JUDGE CHAPPELL: Go ahead.
- 9 MS. FABISH: Thank you.
- 10 BY MS. FABISH:
- 11 O. Hello again, Dr. Geltosky.
- 12 A. Good afternoon.
- 13 Q. I have just handed you a binder of documents. I
- 14 don't think we will need those for quite a while, but we
- 15 will reference them later.
- 16 A. So I should hold them for now?
- 17 O. You can set them to the side. Thank you.
- I would like to start by clarifying what -- the
- 19 scope of what it is you're opining on in this matter and
- 20 confirm some of the opinions that you are not offering.
- 21 You do not have an opinion on whether Endo's
- 22 profit-sharing rights under the DCA justified its
- 23 payment obligations under the DCA, correct?
- 24 A. That's correct.
- 25 Q. So you don't have any opinion as to what the

- 1 market price for the profit-sharing rights that Endo
- 2 acquired under the DCA would be, correct?
- 3 A. Correct. That was not part of my analysis.
- 4 Q. So you have no opinion?
- 5 A. Right.
- 6 Q. Okay. And earlier you criticized Endo's
- 7 valuation analysis of the DCA and IPX-203 and the way it
- 8 calculated a net present value, but you did not
- 9 calculate a net present value for the DCA at the time it
- 10 was executed, did you?
- 11 A. That is correct.
- 12 Q. What about a sensitivity analysis regarding the
- 13 DCA?
- 14 A. I did not do that. I would know how to do it.
- 15 I would actually be quite interested in doing one, but
- 16 you need to have other information available to you to
- 17 do it properly.
- 18 O. In fact, you did not conduct any valuation
- 19 analyses of the DCA at all. Is that correct?
- 20 A. In a strict sense, that's correct.
- 21 Q. So you don't have any opinion at all as to the
- 22 actual value of the DCA to Endo at the time it was
- 23 executed, correct?
- 24 A. That is correct.
- 25 Q. Okay. And you don't -- also don't have an

- 1 opinion on whether Endo should have entered into the
- 2 DCA, correct?
- 3 A. That was not part of my assignment.
- 4 O. So is that a no?
- 5 A. That is a no.
- 6 Q. Okay. And you don't have an opinion on whether
- 7 Endo's decision to enter into the DCA reflects sound
- 8 business judgment, do you?
- 9 A. That was not part of my assignment.
- 10 Q. So, I'm sorry, would you please just answer yes
- 11 or no? Is that a no or a yes?
- 12 A. Well, I have my own opinions, but this was not
- 13 part of the project that I undertook.
- Q. So your opinions in this matter do not include
- 15 an opinion as to whether or not Endo exercised sound
- 16 business judgment in entering into the DCA.
- 17 A. That's not part of my opinion.
- 18 Q. Okay.
- 19 JUDGE CHAPPELL: So we're clear on the record,
- 20 are you asking the witness if he has an opinion or
- 21 formed an opinion or if he has an opinion that was
- 22 included in his expert report in this case?
- 23 MS. FABISH: I'm asking him to confirm whether
- 24 he's offering an opinion in this case on these topics.
- 25 JUDGE CHAPPELL: Do you understand that, sir?

- THE WITNESS: Yes. I think it's obvious in my
- 2 report that I did not offer an opinion.
- 3 BY MS. FABISH:
- 4 O. Okay. So based on that --
- 5 JUDGE CHAPPELL: But the -- she has the right to
- 6 question you about your opinion. That's what she's
- 7 doing.
- 8 THE WITNESS: I'm sorry?
- 9 JUDGE CHAPPELL: She has the right to question
- 10 you about your opinion.
- 11 THE WITNESS: Okay.
- 12 JUDGE CHAPPELL: And when she says did you
- 13 express an opinion, it doesn't mean you did anything
- 14 wrong. She's just looking for a yes or a no.
- 15 THE WITNESS: Well, no.
- 16 BY MS. FABISH:
- 17 Q. Thank you.
- 18 So based on that clarification, would you like
- 19 to clarify any of your previous answers?
- 20 A. That is correct.
- Q. Okay. And you also do not offer an opinion in
- 22 this case as to -- about the termination of the DCA. Is
- 23 that correct?
- 24 A. That's correct.
- 25 Q. And you have no opinion on whether the DCA was a

- 1 bona fide scientific collaboration. Is that correct?
- A. Correct.
- 3 Q. And you don't have an opinion on whether Endo
- 4 exercised good business judgment in its due diligence of
- 5 the DCA. Is that correct?
- 6 A. That is correct.
- 7 JUDGE CHAPPELL: You need to be careful how
- 8 you're phrasing that. The man said he's got 37 years'
- 9 experience. He might have an opinion. The way you've
- 10 phrased that, he could say, "Hell, yeah, I've got an
- 11 opinion and here it is." So just be careful what you're
- 12 asking the expert.
- MS. FABISH: Okay. Thank you for that
- 14 clarification. I'll rephrase.
- 15 BY MS. FABISH:
- 16 Q. Are you offering an opinion in this matter as to
- 17 whether Endo exercised good business judgment in its due
- 18 diligence under the DCA?
- 19 A. No.
- 20 Q. Okay, thank you.
- 21 I'd like to talk for a little bit about the
- 22 basis for your opinions that you do offer in this
- 23 matter, and you testified earlier that you base your
- 24 opinions primarily on your experience in the industry.
- 25 Is that correct?

- 1 A. Correct.
- Q. Okay. You've never worked at Endo, right?
- 3 A. That is correct.
- 4 Q. You've also never worked at Impax?
- 5 A. Correct.
- 6 Q. And you've never done any consulting work
- 7 regarding the DCA prior to your work as an expert on
- 8 this matter?
- 9 A. That's correct.
- 10 Q. And all the information that you have about the
- 11 DCA was gleaned from your review of documents and
- 12 testimony in this matter. Is that correct?
- 13 A. Excuse me. Correct.
- 14 Q. Okay. Have you ever met any of the individuals
- 15 whose testimony you read?
- 16 A. No.
- 17 Q. Okay. Have you ever met any of the individuals
- 18 whose emails you reviewed?
- 19 A. Never met them.
- Q. Okay. Do you rely on any treatise or secondary
- 21 sources in forming your opinion in this matter?
- 22 A. No.
- Q. Does your expert report contain a complete list
- 24 of the documents and testimony that you considered in
- 25 reaching your opinions?

- 1 A. Yes.
- Q. Okay. And as well as a complete statement of
- 3 the bases for those opinions?
- 4 A. Yes.
- Q. And it appears that the vast majority of the
- 6 materials listed in your report -- if you would like to
- 7 refer to it, you may, but you don't need to, it's tab 1
- 8 in the binder that I've provided you -- the materials
- 9 listed in Exhibit B as having been considered, by my
- 10 count, only 14 of the 198 materials listed there are not
- 11 Endo or Impax business documents. Does that sound about
- 12 right to you?
- 13 A. I'm not sure what you're referring to right now.
- 14 Q. Okay. If you take a look at Exhibit B to your
- 15 report, there's a list of materials --
- 16 A. In my -- wait a minute, in my -- not in this
- 17 notebook?
- 18 Q. Exhibit B to your expert report, which is tab 1
- 19 in the notebook that I've provided you.
- 20 A. Okay, tab 1 has my expert report, yes. Wait a
- 21 minute, this is not the expert report. Yes, it is.
- 22 Sorry.
- 23 O. And your Exhibit F begins on page CX 5003-60.
- 24 It's entitled "List of Materials Considered." Let me
- 25 know when you get there.

- 1 And so looking at this list of -- of the
- 2 materials that you considered, it seems to me that the
- 3 vast majority, all but about 14 of them, are Endo or
- 4 Impax business documents. Is that correct?
- 5 A. Yes.
- 6 Q. And the remaining 14 -- and I'm looking
- 7 specifically, to help you answer this question, at the
- 8 section entitled "Public Documents," right around page
- 9 5003-65 -- are SEC filings or websites and a few things
- 10 it looks like you pulled off the Internet. Is that
- 11 correct?
- 12 JUDGE CHAPPELL: Wait until he's on the page.
- 13 You changed pages, didn't you?
- 14 MS. FABISH: Of course. Thank you.
- 15 BY MS. FABISH:
- 16 Q. Page -065.
- 17 A. Yes, I am on that page. What's your question,
- 18 please?
- 19 Q. So beyond the Impax and Endo business documents,
- 20 it looks like you relied upon a few SEC filings,
- 21 websites, and a few things that you pulled off the
- 22 Internet. Is that correct?
- 23 A. That is correct.
- Q. Thank you.
- 25 So in forming your opinions in this matter, it

- 1 looks like you compared the business documents provided
- 2 to you by counsel against your experience in the
- 3 industry. Is that fair to say?
- 4 A. Yes.
- 5 Q. Okay. Now, I think it's implied from your
- 6 testimony a moment ago, but just to be clear, you did
- 7 not perform any empirical analyses, such as valuation
- 8 analyses, net present value calculations, things like
- 9 that, in reaching your opinions that you offer in this
- 10 matter, correct?
- 11 A. Well, I was able to look at the sheets provided
- 12 in the OEW and based that on my conclusion. I actually
- 13 started to do an NPV calculation, but if you look at
- 14 that OEW, it basically doesn't have enough information
- 15 there to properly perform one.
- 16 Also, so I could do that -- you know, actually,
- 17 I can't do it, because it ends. The dates -- they refer
- 18 to, I think, 2031 or something like that, but the --
- 19 which they used to calculate their NPV, but they don't
- 20 have data to support those outyears.
- 21 The other thing, why I decided I -- I should not
- 22 even bother in calculating the NPV is I didn't trust the
- 23 revenue lines at all. There is no market research, no
- 24 sensitivity analyses. These are just random numbers as
- 25 far as I was concerned. So I just didn't feel that it

- 1 was worth my time.
- Q. So just to make sure the record's clear, you did
- 3 not perform any empirical analyses, correct?
- 4 A. No. I used common sense, just looking at it,
- 5 and came up with my conclusion.
- 6 Q. Thank you.
- 7 So you've read some documents and testimony by
- 8 people you have never met, and you are telling us what
- 9 you think about them based on your experience in the
- 10 industry, right?
- 11 A. No. I'm not saying what -- your question,
- 12 again, is what I think about those people --
- 13 Q. No.
- 14 A. -- without having met them?
- 15 Q. No, I'm sorry.
- 16 JUDGE CHAPPELL: Wait, wait, wait. Let him
- 17 finish, and let her finish.
- 18 THE WITNESS: So as I understood your question,
- 19 you're asking me, I formed an opinion on these people
- 20 based on -- whom I've never met? I haven't formed any
- 21 opinion on these people.
- 22 BY MS. FABISH:
- 23 Q. You're right. My question was unclear. I'll be
- 24 happy to rephrase.
- 25 You've read documents drafted by people that

- 1 you've never met and you are telling us what you think
- 2 about those documents based on your experience in the
- 3 industry. Is that correct?
- 4 A. That's correct.
- 5 Q. Okay.
- 6 JUDGE CHAPPELL: That's better. The question
- 7 you worded before, you said "what you think of them,"
- 8 and it could have referred to the documents or the
- 9 testimony of the people.
- 10 MS. FABISH: Indeed. No, I understand now.
- 11 Thank you for clarifying.
- 12 BY MS. FABISH:
- Q. I'd like to talk a little bit now -- switch
- 14 gears and talk about risk, something that you discussed
- 15 quite a bit with Complaint Counsel earlier today.
- 16 Do you agree that all pharmaceutical development
- 17 has an inherent element of risk?
- 18 A. Yes.
- 19 Q. And that's true at all stages of development,
- 20 just to varying degrees, correct?
- 21 A. That's correct.
- 22 Q. Okay. And earlier today you testified that
- 23 co-promotion agreements involved risk and profit-sharing
- 24 elements. Is that correct?
- 25 A. Well, they involve risk and, yes, there is a

- 1 profit-sharing component to the agreements, yes.
- 2 Q. And the DCA was a way for Impax and Endo to
- 3 share the risks and costs associated with developing
- 4 IPX-203, right?
- 5 A. Correct.
- Q. Okay. Now, under the DCA, Endo did not agree to
- 7 take on all of the development costs for 203. Is that
- 8 right?
- 9 A. That's correct, yeah.
- 10 Q. Okay. And in terms of how much Endo was
- 11 obligated to support the cost of 203 development under
- 12 the DCA, that amount would be capped at the total amount
- 13 of milestone payments listed in the agreement. Is that
- 14 correct?
- 15 A. That's correct.
- 16 Q. Okay. But Impax remained responsible for
- 17 performing all of the development work, right?
- 18 A. That's correct.
- 19 Q. Okay. So if Impax's development costs exceeded
- 20 the amount that Endo contributed under the DCA, Impax
- 21 would be responsible for covering all of those costs,
- 22 correct?
- 23 A. Presumably. That was not articulated in the
- 24 DCA. Sometimes agreements of that sort would have
- 25 language that -- and this -- there's actually a real

- 1 peculiarity to this agreement. Most of these agreements
- 2 are budget-based. There's no budget. They don't share
- 3 a budget. Most agreements, we're going to fund --
- 4 Company A will say I'll fund this much, Company B will
- 5 say they'll fund that much, and they agree to that
- 6 budget. This is a very unique way of paying -- for Endo
- 7 to be paying their portion of the development. So it's
- 8 left hanging, what happens if expenses get more than
- 9 whatever.
- 10 Q. But to the extent that Impax's development costs
- 11 exceeded the amount Endo contributed under the DCA, Endo
- 12 would not have any responsibility for those additional
- 13 costs.
- 14 A. Not as the contract is worded, as-is, yes.
- 15 Q. So just by way of illustration, if Impax
- 16 succeeded in completing Phase II clinical trials with
- 17 IPX-203, but development was unsuccessful beyond that,
- 18 Endo would only pay Impax a total of 20 million,
- 19 including the up-front payment, regardless of how much
- 20 it cost Impax to reach that milestone. Is that right?
- 21 A. That's right. That is a very ambiguous
- 22 statement in --
- 23 JUDGE CHAPPELL: Hold on there, sir. I let you
- 24 ramble on in the last answer, where you said
- 25 "Presumably," and then you went on for, like, 20 lines

- 1 after that. It seems like you are going to say the same
- 2 thing here. So I don't want to be here until midnight.
- 3 So please listen to the question, and when you've
- 4 answered it, that's enough. "That's right," that's your
- 5 answer. You didn't need to go further.
- 6 THE WITNESS: Could you rephrase -- restate your
- 7 question, please?
- 8 BY MS. FABISH:
- 9 Q. Just by way of illustration, if Impax succeeded
- 10 in completing Phase II clinical trials of IPX-203, the
- 11 development was unsuccessful beyond that, Endo would
- 12 only pay Impax a total of 20 million, including the
- 13 up-front payment, regardless of how much it cost Impax
- 14 to reach that milestone, correct?
- 15 A. That is correct. Sorry for misunderstanding
- 16 your question.
- 17 Q. Thank you.
- And just by way of illustration, again, if Impax
- 19 were able to successfully bring 203 to market but it
- 20 cost Impax \$100 million to get there, Endo's
- 21 contribution would be limited to a maximum of 40 million
- 22 of that -- maximum of 40 million of that cost, correct?
- 23 A. Correct.
- 24 Q. Okay. And regardless of the cost of development
- 25 to Impax, Endo retains the same profit-sharing rights.

- 1 Is that right?
- A. Yes.
- Q. Do you recall what Impax estimated its costs to
- 4 be of developing IPX-203?
- 5 A. There was a statement that I saw of roughly --
- 6 between 80 and 100 million dollars.
- 7 O. And --
- 8 A. That's only an estimate, though.
- 9 Q. Thank you.
- 10 And, Dr. Geltosky, you don't have an opinion
- 11 on -- you don't offer an opinion in this case as to
- 12 whether these risk- and profit-sharing provisions under
- 13 the DCA favor Impax or Endo, do you?
- 14 A. That's correct.
- 15 Q. Okay. I'd like to shift gears a little bit now
- 16 and speak to you about your opinions regarding the \$10
- 17 million up-front payment portion of the DCA. In your
- 18 report and prior testimony, you offered the opinion that
- 19 the \$10 million milestone payment was unusually large
- 20 for a development-stage drug product at the stage that
- 21 203 was in.
- To clarify, by "unusually large," you mean
- 23 different than what you would expect based on your
- 24 experience in the pharmaceutical industry, correct?
- 25 A. Correct.

- 1 Q. Okay. And I'm referring here specifically to
- 2 the language that was in your report. You say
- 3 "unusually large for a development-stage drug." I
- 4 believe you've already clarified this in your earlier
- 5 testimony, but just to make sure, you're referring there
- 6 specifically to the fact that IPX-203 was in nonlead
- 7 discovery stage, that no lead drug had yet been
- 8 identified. Is that right?
- 9 A. That's right.
- 10 Q. Okay. And in reaching your conclusion that the
- 11 \$10 million payment was different than what you would
- 12 expect based on your experience in the pharmaceutical
- 13 industry, did you review any pharmaceutical agreements
- 14 besides the DCA?
- 15 A. Just relying on my experience and reading of --
- 16 you know, constant reading of the literature, what deals
- 17 go for.
- 18 Q. So is that a yes or a no?
- 19 A. Pardon me?
- Q. Is that a yes or a no? Did you review other --
- 21 other deals besides --
- 22 A. On an ongoing basis, I'm -- yes. So I did
- 23 review other things on an ongoing basis which informed
- 24 my opinion on this, my years of reading, every day, IO
- 25 World, Fierce, et cetera.

- 1 JUDGE CHAPPELL: The question, sir, was any
- 2 pharmaceutical agreements besides the DCA.
- 3 THE WITNESS: Just my recollections of the
- 4 agreements that I was involved in.
- 5 BY MS. FABISH:
- 6 Q. Okay. But you did not actually review any
- 7 agreements in the process of forming these opinions.
- 8 A. No.
- 9 Q. Thank you.
- 10 So I take it, then, you also did not compare the
- 11 payment terms in any other agreements to the ones that
- 12 are in the DCA, correct?
- 13 A. Correct.
- 14 Q. And, in fact, you don't consider such a
- 15 comparative analysis to be necessary to reach your
- 16 opinions on what is typical in a pharmaceutical
- 17 collaboration agreement, correct?
- 18 A. I'm sorry? State it again.
- 19 Q. You don't consider such a comparative analysis
- 20 between the DCA and other pharmaceutical agreements to
- 21 be necessary to reach your opinions on what is typical
- 22 in a pharmaceutical collaboration agreement, correct?
- 23 A. No. Again, I'm relying on my memory and
- 24 knowledge of the agreements I was involved in, and I
- 25 compare and contrast.

- 1 Q. And when we met last month and I deposed you, I
- 2 believe you described reviewing such additional
- 3 agreements and comparing them to the DCA as something
- 4 that would have been a waste of your time in reaching
- 5 your opinions in this matter. Is that correct?
- 6 A. I don't recall saying that.
- 7 Q. Would you like to review your transcript to
- 8 determine is that -- well, strike that. I'll back up.
- 9 Do you agree with that statement now? Do you
- 10 believe it would be a waste of your time to do that in
- 11 reaching your opinions in this matter?
- 12 A. Yes. I'll stand by it.
- 13 Q. Now, when you were speaking earlier today with
- 14 Complaint Counsel, you were discussing the different
- 15 roles that you've played in your experience in various
- 16 organizations and companies, and it sounds like the bulk
- 17 of your experience assessing a pharmaceutical product or
- 18 product candidate for potential investment comes from
- 19 your time at Bristol-Myers Squibb and SmithKline
- 20 Beecham. Is that correct?
- 21 A. The majority, yes.
- 22 Q. So you can't speak to whether the universe of
- 23 companies smaller than big pharma companies like
- 24 SmithKline Beecham and Bristol-Myers Squibb might take a
- 25 different approach to assessing discovery-stage products

- 1 than do those larger companies.
- 2 A. No, because I've worked with smaller companies
- 3 as a consultant, and I know what their processes are, I
- 4 know what questions they ask, and they're just the same
- 5 types of questions that, again, midsize pharma would ask
- 6 and how they would go about their evaluation. So that
- 7 is based on real, live experience as a consultant.
- 8 JUDGE CHAPPELL: Hold on a sec. Are you saying
- 9 you've negotiated agreements like the one in this case?
- 10 THE WITNESS: Not exactly like this one, no.
- 11 JUDGE CHAPPELL: All right.
- Go ahead.
- 13 BY MS. FABISH:
- 14 Q. Is that what you told me when I asked you a
- 15 similar question at your deposition last month, do you
- 16 recall?
- 17 A. You'll have to ask that question.
- 18 Q. Sure. If you could take a look at tab 2 in your
- 19 binder, which is a copy of the transcript of your
- 20 deposition, and I would direct you to page 167 of that
- 21 deposition. You'll need to look at the little page
- 22 numbers. You'll see there's four pages to a page. I'm
- 23 referring to the...
- 24 A. Yes.
- 25 Q. And beginning on line 1:

- 1 "QUESTION: Might a company that is smaller than
- 2 Glaxo, than SmithKline Beecham or Bristol-Myers Squibb,
- 3 take a different approach to considering discovery-stage
- 4 products?"
- 5 Then Mr. Butrymowicz objected.
- 6 "ANSWER: Yeah, I can't speak to the whole
- 7 universe of those companies."
- 8 Do you see that?
- 9 A. Yes.
- 10 Q. Based on reviewing your prior testimony, as you
- 11 sit here today, is it true that you cannot speak to
- 12 whether the universe of companies smaller than big
- 13 pharma companies like SmithKline Beecham or
- 14 Bristol-Myers Squibb might take a different approach to
- 15 assessing discovery-stage products than do those larger
- 16 companies?
- 17 A. The universe is pretty large, so I can't
- 18 possibly know everything in the universe of companies.
- 19 Q. So that's a yes?
- 20 A. And your question is?
- 21 Q. Saying it's -- is it true that you cannot speak
- 22 to that universe of smaller companies?
- 23 A. Yes.
- Q. Okay. Now, you testified earlier today as well
- 25 that during your work at Arizona State, you did quite a

- 1 bit of work on early-stage development assets, and
- 2 you've previously testified that you've only actually
- 3 worked on one deal in which the potential subject
- 4 product may not have had a lead drug identified. Is
- 5 that correct?
- 6 A. At Arizona State?
- 7 Q. Just generally.
- 8 A. I'm sorry, say your question again, please.
- 9 Q. I'll just back up and rephrase. I think perhaps
- 10 I can ask a better question.
- 11 You've only worked on one deal in your career in
- 12 which the potential subject product may not have had a
- 13 lead drug identified, correct?
- 14 A. There were probably more than one.
- 15 Q. Can you recall more than one as you sit here
- 16 today?
- 17 A. I can't remember exact numbers, but there were a
- 18 handful, a few.
- 19 Q. Do you recall what you told me during your
- 20 deposition last month regarding your prior experience?
- 21 A. Yes, yes, um-hum.
- 22 Q. What do you recall about that?
- 23 A. I limited it, I believe, to one or -- yeah.
- Q. But today you're saying you recall a handful?
- 25 A. A few more, right.

- 1 O. A few more.
- 2 A. Right, yeah.
- Q. Do you recall whether you calculated a net
- 4 present value for the product involved in that one or
- 5 potentially few deals involving a nonlead drug asset?
- 6 A. No.
- 7 O. And in reaching your opinions that you offer in
- 8 this matter, did you look into whether Endo has either
- 9 invested in or collaborated on discovery-stage
- 10 pharmaceutical products in the past?
- 11 A. I believe they -- I believe they have had a
- 12 couple relationships with very early-stage technologies.
- 13 I can't think of the concrete numbers, but I seem to
- 14 recall, in reading the materials, that they had.
- 15 Q. Did you review any information as to how Endo
- 16 structured such deals?
- 17 A. I seem to recall that the payments were quite a
- 18 bit less, but this -- this is -- a lot -- I've reviewed
- 19 a lot of information, so I'm a little bit uncertain.
- 20 But that's my best recollection, that they were paying
- 21 much smaller dollars.
- 22 Q. So sitting here today, what can you tell me
- 23 about the information you recall about this
- 24 discovery-stage product -- these discovery-stage
- 25 products that Endo considered investing in?

- 1 A. They were -- there were only a few of them, and
- 2 I believe they were roughly, you know, as early stage as
- 3 this, maybe even earlier -- well, not earlier than this,
- 4 nothing's earlier than this. And I believe the payments
- 5 were actually pretty small, but I don't -- I don't have
- 6 a great recollection.
- 7 O. And you couldn't point me to where in the
- 8 materials you reviewed you saw this information?
- 9 A. No.
- 10 Q. And you couldn't point me to a portion of your
- 11 report that provides that information either?
- 12 A. That's correct.
- 13 Q. Is it your opinion that collaborations regarding
- 14 discovery-stage pharmaceutical candidates are generally
- 15 too risky for companies to enter into in any form?
- 16 A. No. People do it all the time.
- 17 Q. Okay. I'd like to shift gears again and focus
- 18 again on the payment amount. Part of the basis for your
- 19 opinion, you described earlier that the \$10 million
- 20 payment was unusually large for a deal of that stage --
- 21 a deal regarding an asset at that stage, was the amount
- 22 of risk that you saw in the deal given IPX-203's stage
- 23 of development. Is that correct?
- 24 A. That's correct.
- 25 Q. And we previously established that the lack of a

- 1 lead drug was the primary source of the risk that you
- 2 saw, correct?
- 3 A. Yes, and I have had more time to think on that
- 4 topic.
- 5 Q. I'm sorry? I didn't hear you.
- 6 A. I have had more time to think on that topic of
- 7 risk related to 203, and I still keep my same
- 8 conclusion, that it's a very risky project.
- 9 Q. Thank you.
- 10 But you haven't attempted to quantify that risk.
- 11 Is that right?
- 12 A. I haven't -- no, I haven't tried to quantify it, 13 no.
- 14 Q. You also didn't perform any actual calculations
- 15 to determine what payment amount would, in your view,
- 16 account for the risk that you perceived in the DCA,
- 17 correct?
- 18 A. That's correct.
- 19 Q. And you discussed earlier today your criticisms
- 20 of Endo's due diligence efforts in part because you felt
- 21 that Endo did not adequately account for risk, but you
- 22 agree there are different approaches to calculating a
- 23 risk-adjusted value of a potential asset in a
- 24 pharmaceutical collaboration, correct?
- 25 A. There are -- the benchmark is the -- is the

- 1 calculation of the -- of the rNPV, which is very
- 2 straightforward.
- 3 Q. Are there -- do you agree that there are
- 4 different ways to assess risk?
- 5 A. Yeah, there are a couple different ways. The --
- 6 one of the ways that people do it, which is erroneous,
- 7 is they don't -- what -- what needs to be done is to
- 8 calculate the technical risk at each stage of
- 9 development. Some people account for that by just
- 10 fooling around with the discount rate, increasing it or
- 11 decreasing the discount rate. If you know anything
- 12 about this field, you can go onto the Internet, that's
- 13 not a correct way of doing it. It doesn't properly
- 14 account for all the technical risk.
- There's another way that people calculate NPV
- 16 using a so-called Monte Carlo analysis, which is very
- 17 complex and most people don't use it.
- 18 O. So if I can just remind you to please keep in
- 19 mind His Honor's instruction to answer yes or no
- 20 questions with just yes or no so we can move our
- 21 examination along.
- 22 A. Well, I think that yes and no needs to be
- 23 qualified sometimes.
- Q. Okay. Do you agree there are different
- 25 approaches to calculating a risk-adjusted net present

- 1 value?
- 2 A. Yes, as I just described.
- 3 Q. And do you agree there are different approaches
- 4 to calculating a risk-adjusted internal rate of return?
- 5 A. Yes.
- 6 Q. Do you hold any degrees in accounting?
- 7 A. No.
- 8 Q. Any degrees in finance?
- 9 A. No.
- 10 Q. Any degrees in business?
- 11 A. Not a -- no, not a formal degree.
- 12 O. In reviewing the materials -- strike that.
- In forming your opinions that you offer in this
- 14 matter, did you see any evidence suggesting that Endo
- 15 asked for information from Impax during diligence and
- 16 Impax refused to provide it?
- 17 A. No. Excuse me, no.
- 18 Q. Turning back to the payment size, you've
- 19 testified that -- strike that.
- 20 You do not view anticipated R&D costs of a
- 21 subject product as relevant to determining the
- 22 appropriate payment amount in a pharmaceutical
- 23 collaboration, correct?
- 24 A. Sorry, say that -- state it again.
- 25 Q. You do not view anticipated R&D costs of a

- 1 subject drug product as relevant to determining the
- 2 appropriate payment amount in a pharmaceutical
- 3 collaboration. Is that correct?
- 4 A. No, no.
- 5 Q. Okay. But in your report and in your prior
- 6 testimony, you've offered no other metric for assessing
- 7 the payment size under the DCA, other than comparing it
- 8 generally with your experience in the industry. Is that
- 9 correct?
- 10 A. That's correct.
- 11 O. I'd like to talk a little bit about IPX -- the
- 12 IPX-066 information that Endo reviewed in connection
- 13 with its due diligence. You criticized the way that
- 14 Endo worked with information about 066 in assessing
- 15 IPX-203. I think that's fair to say, right?
- 16 A. Yes.
- 17 Q. But commercial market information about 066
- 18 would be relevant in assessing 203, would it not?
- 19 A. Only in part.
- 20 O. Okay. Commercial market information about 066
- 21 would, in fact, address some of the key variables of
- 22 performance for 203, would it not?
- 23 A. No.
- 24 O. It would not?
- 25 A. No, because 203 is going to behave differently

- 1 from 066, so...
- Q. When I deposed you in September, sir, do you
- 3 recall me asking you a similar question?
- 4 A. No, I don't.
- 5 Q. Would you mind turning to tab 2 again, which is
- 6 a copy of your deposition transcript, specifically the
- 7 mini page 135. Let me know when you're there.
- 8 A. Okay. I'm there, yep.
- 9 Q. Looking at line 7.
- 10 A. Page 135, line 7? "With many degrees -- do you
- 11 have many degrees" --
- 12 Q. I apologize. Hold on. My numbering is off
- 13 here.
- 14 You know, I apologize, I have an incorrect cite,
- 15 so we will just come back to that later.
- 16 My apologies for the delay. We may just need to
- 17 come back to that later, so you can strike that question
- 18 for now.
- 19 The disease -- so turning back, the information
- 20 about IPX-066, the disease parameters and background of
- 21 IPX-066 would be relevant in assessing 203, would they
- 22 not?
- 23 A. That's true.
- Q. Okay. And IPX-066 and IPX-203 were likely to
- 25 follow a similar clinical development program. Is that

- 1 correct?
- 2 A. Yes.
- 3 Q. So information about the 066 clinical
- 4 development program would also be relevant to assessing
- 5 203, correct?
- 6 A. Not -- not really.
- 7 Q. So even though the two drugs were going to
- 8 follow a similar clinical development program, you don't
- 9 view information about the 066 clinical development
- 10 program as relevant to assessing 203.
- 11 A. Right. The data that comes out of the 066
- 12 clinical trial has no bearing at all on the data that
- 13 would come out of the 203 clinical trial. Different
- 14 drugs. Different responses in patients.
- 15 Q. Okay. I would like to turn back to my question
- 16 from before when I had a technical difficulty, and I
- 17 would like to ask you again whether -- I asked you
- 18 whether commercial market information about IPX-066
- 19 would be relevant to -- would address some of the key
- 20 variables of performance for 203, and I'd like to refer
- 21 you to page 133 of your deposition, which is located --
- MR. BUTRYMOWICZ: Your Honor, I would object. I
- 23 don't think that's the question that he was asked
- 24 earlier.
- 25 MS. FABISH: I'm happy to read it back. I

- 1 didn't intentionally change the question. So maybe I
- 2 will just ask a new question, and we'll start all over,
- 3 to simplify things.
- 4 BY MS. FABISH:
- 5 Q. Dr. Geltosky, do you view commercial market
- 6 information about 066 as addressing some of the key
- 7 variables of performance for 203?
- 8 A. Well, in the sense of the uphill burden, et
- 9 cetera, yes. So those are the -- they identify the
- 10 parameters.
- 11 Q. Okay, thank you.
- 12 A. Yep.
- 13 Q. And you would acknowledge that Impax viewed
- 14 IPX-203 as a potential franchise extender for the 066
- 15 franchise, correct?
- 16 A. Correct.
- 17 Q. And Endo understood that it was intended as a
- 18 line extension of 066 as well, correct?
- 19 A. I don't recall those words, but I think yes
- 20 would be the answer.
- 21 Q. What do you understand a line extension to be
- 22 referring to?
- 23 A. It would be basically a product in the same
- 24 category that one would use because it had maybe patent
- 25 protection, whereas the original didn't have any more

- 1 patent protection, or it had some superior performance
- 2 to the original and it basically just kept the franchise
- 3 going.
- 4 Q. And by "kept the franchise going," what do you
- 5 mean?
- 6 A. Well, that they would still play a role in the
- 7 treatment of Parkinson's disease; that they would have,
- 8 you know, maybe more than one drug to be able to offer
- 9 physicians.
- 10 Q. And so given that 203 was going to be a
- 11 franchise extender for 066, in modeling how IPX-203
- 12 might perform in the market, Impax and Endo would have
- 13 used 066 as kind of a benchmark to try and improve upon.
- 14 Is that correct?
- 15 A. Ah, yes.
- 16 Q. And, Dr. Geltosky, even assuming that the
- 17 subject of the DCA negotiations changed in the way that
- 18 you described in your testimony earlier today, from 066
- 19 to 203, would at least some of the information about
- 20 IPX-066 still be relevant for assessing IPX-203 in the
- 21 ways we just discussed?
- 22 A. As it turns out, not really, because the
- 23 performance -- you have to wait to see -- they -- there
- 24 was not enough clinical data in my view at the time for
- 25 Endo to have any degree of confidence that they -- that

- 1 203 would be able to be superior to it.
- 2 O. So I want to make sure that I am making my
- 3 question clear. So I asked you a series of questions
- 4 just a moment ago about whether or not certain aspects
- 5 of information about 066 would be relevant to assessing
- 6 IPX-203, and in a few instances, at least, you agreed
- 7 with me that, yes, that information would be relevant.
- 8 Do you recall that?
- 9 A. Yes.
- 10 Q. And I am asking you now, even if at one point
- 11 the parties were focused on 066 and then they changed to
- 12 focusing on 203, even if that is true, would that
- 13 information about 066 that we just discussed remain
- 14 relevant to an assessment of 203?
- 15 A. Well, it would set a baseline, yeah, but I don't
- 16 think there were enough data available to, you know,
- 17 hang your hat on at that point. You need to do a Phase
- 18 III, which they hadn't done yet.
- 19 Q. So is that a yes?
- 20 A. A partial yes.
- 21 Q. Okay, thank you.
- 22 And speaking more generally for a moment, in
- 23 conducting due diligence on a candidate drug, it's
- 24 useful to consider information about drugs with which
- 25 the candidate would compete, correct?

- 1 A. Yes.
- Q. Okay. And that's true for both potential
- 3 competitors who might already be on the market as well
- 4 as any potential competitors that you understand are in
- 5 the pipeline of other companies, correct?
- 6 A. That's correct.
- 7 O. And the kinds of information about those
- 8 potential competitors that you might look at would
- 9 include safety and efficacy information, correct?
- 10 A. Correct.
- 11 Q. Now, the IPX-203 product covered by the DCA
- 12 would potentially compete with Impax's 066. Is that
- 13 correct?
- 14 A. That's correct.
- 15 Q. Okay. And the information about 066 that Impax
- 16 provided Endo included safety and efficacy data on 066,
- 17 did it not?
- 18 A. It had -- yes, it had partial data sets, I would
- 19 call it.
- 20 Q. Okay. Do you recall that Impax provided Endo
- 21 access to a data room of information about IPX-066?
- 22 A. Yes.
- 23 O. And you viewed that data room of information as
- 24 pretty comprehensive, correct?
- 25 A. Yeah. The headline topics were correct, yeah.

- 1 Q. So, for example, that data room included -- we
- 2 already established -- clinical information including
- 3 safety and efficacy data, correct?
- 4 A. Correct.
- 5 Q. And information on the IP landscape?
- 6 A. I'm sorry? Say that again.
- 7 Q. Excuse me. Information on the IP landscape?
- 8 A. I don't recall that. It was a big list of -- of
- 9 file folders to review. I don't recall that
- 10 specifically.
- 11 Q. I'd like to turn to tab 5 of your binder.
- 12 Perhaps I can help you. Turning -- this is RX 272, and
- 13 turning to page RX 272.0005 --
- 14 A. Yes.
- 15 Q. -- do you see a portion entitled "Legal Folder"?
- 16 Based on reviewing this document, do you recall whether
- 17 the data room that Impax provided Endo access to
- 18 included information about IP landscape?
- 19 A. There are two documents in there that would fall
- 20 in that category.
- 21 O. How about information on technical due
- 22 diligence, did the data room include that type of
- 23 information?
- 24 A. Yes.
- 25 Q. And information on financial analysis, did it

- 1 include that information?
- 2 A. Financial? Yes.
- 3 Q. All right, thank you. You can set that aside.
- 4 So I'd like to talk a little bit about your
- 5 opinions regarding Endo specifically. You testified
- 6 earlier that you've never worked or consulted for Endo,
- 7 right?
- 8 A. That's correct.
- 9 Q. And, in fact, you do not have any information
- 10 about Endo's business practices that you didn't glean
- 11 from documents you received from counsel in this matter,
- 12 correct?
- 13 A. I believe, as I testified during my deposition,
- 14 I was aware of their shift in focus, which was going
- 15 over to so-called men's health.
- 16 Q. And what was that -- that knowledge based on?
- 17 A. As I testified prior, I don't really recall. I
- 18 mean, I live in a community that contains Endo. It
- 19 could have been in the Philadelphia Inquirer, could have
- 20 been places like that.
- Q. Any other sources of information?
- 22 A. No.
- 23 Q. Okay. Yet you do offer an opinion as to whether
- 24 Endo's diligence on the DCA was consistent with Endo's
- 25 business development practices, correct?

- 1 A. Yes.
- Q. Okay. And your understanding of Endo's process
- 3 for diligence in deals comes from a review of Endo's
- 4 documents describing that process, correct?
- 5 A. Correct.
- 6 Q. And, in fact, it's -- it's really just one
- 7 document, isn't it?
- 8 A. There were a number of slides in that slide deck
- 9 that I believe referred to -- it had -- they were -- I
- 10 recall two what I would call process maps.
- 11 Q. Okay. But those were all slides in a single
- 12 slide deck, correct?
- 13 A. That's correct.
- 14 Q. Okay. So to form your opinion that Endo did not
- 15 follow its business development procedures, you
- 16 basically read one Endo document from a group of Endo
- 17 documents provided to you by Complaint Counsel and
- 18 concluded that what was described in that document is
- 19 different than what you understood Endo did with the
- 20 DCA. Is that right?
- 21 A. That's correct.
- 22 Q. Okay. And you also offer an opinion that 203
- 23 does not fit within Endo's strategic area of focus. Is
- 24 that right?
- 25 A. That's correct.

- 1 Q. Okay. And you base that conclusion solely --
- 2 you base that conclusion also solely on a review of
- 3 certain Endo documents provided to you by counsel. Is
- 4 that right?
- 5 A. That's correct.
- 6 Q. Okay. And specifically I believe you stated you
- 7 base that conclusion on -- on two things. First, the
- 8 fact that the words "Parkinson's disease" were absent
- 9 from a set of slides or disease areas of interest. Is
- 10 that one reason?
- 11 A. Yes.
- 12 O. Okay. And I believe the other reason was that
- 13 you saw a handful of Endo corporate documents that state
- 14 that Endo was interested in near-term revenue
- 15 generators, correct?
- 16 A. That's correct.
- 17 Q. Nothing else informed your opinion that 203 was
- 18 not a strategic fit for Endo's business?
- 19 A. That's correct.
- 20 Q. Okay. And in reaching that opinion, you didn't
- 21 consider any other deals completed by Endo. Is that
- 22 right?
- 23 A. That's correct.
- Q. Did you consider any deals Endo contemplated but
- 25 didn't complete?

- 1 A. No.
- Q. If you would turn to tab 9 of your binder,
- 3 please. This is a document listed in your materials
- 4 relied upon, the Bates number EPI001448440. Oh, I'm
- 5 sorry -- oh, yeah, this is correct.
- 6 This is CX 1209 that you were discussing earlier
- 7 with Complaint Counsel, and you'll recall the vast
- 8 majority of this document has been designated for in
- 9 camera treatment, so I am going to ask you solely about
- 10 the cover email portion.
- 11 A. Um-hum.
- 12 Q. And I would ask you to please take care to
- 13 respond only with respect to those -- those questions --
- 14 A. Sure.
- 15 Q. -- since we are in open session.
- This is a June 8th, 2010, email from Robert
- 17 Cobuzzi, who was Endo's senior VP of corporate
- 18 development at the time the DCA was executed, to the
- 19 Endo board of directors, announcing that the DCA with
- 20 Impax had been executed.
- 21 I'd like to draw your attention -- actually,
- 22 could we -- could we put that up on the screen, please,
- 23 just the cover email? It's Exhibit Number 1209.
- 24 I'd like to draw your attention to the second
- 25 paragraph that begins with, "This is..."

- 1 A. Um-hum.
- Q. It says, "This is an exciting opportunity for
- 3 Endo as it further builds our product pipeline for the
- 4 future with a drug candidate that fits with our
- 5 commercial footprint."
- 6 Do you see that?
- 7 A. Yes.
- 8 Q. Based on this document, does it appear that
- 9 Endo's senior VP of corporate development in 2010 viewed
- 10 203 as a good strategic fit with Endo's commercial
- 11 goals?
- 12 A. I mean, the use of the term "commercial
- 13 footprint" is pretty vague.
- 14 Q. Is that a yes or a no?
- 15 A. Well, he doesn't really address strategy here.
- 16 So I guess I would say no.
- 17 Q. You don't believe that the statement saying that
- 18 this project fits with our commercial footprint
- 19 indicates that he views 203 as a --
- 20 A. Well, he does, but, I mean, it's -- yes.
- 21 Q. Okay. All right, fine. Do you think you're
- 22 more qualified to assess the fit of the DCA with Endo's
- 23 strategic business goals as of 2010 than is the VP of
- 24 Endo in 2010?
- 25 A. I'm sorry?

- 1 Q. Do you feel that you are more qualified to
- 2 assess the strategic fit of the DCA with Endo's
- 3 strategic business goals as of 2010 than was the VP of
- 4 corporate development at Endo in 2010?
- 5 A. No.
- 6 Q. In preparing your report more generally -- you
- 7 can set that aside. Thank you.
- 8 In preparing your report more generally, you
- 9 considered -- did you consider various other opportunity
- 10 evaluation worksheets for products Endo was considering
- 11 collaborating on?
- 12 A. Yes, I did.
- 13 Q. Okay. And you viewed those documents as
- 14 consistent with your opinions that you offer in this
- 15 matter, correct?
- 16 A. I don't understand that question.
- 17 Q. I'll rephrase.
- 18 Did you see anything in those documents that was
- 19 inconsistent with the opinions that you offer in this
- 20 case?
- 21 A. Well, the other OEWs that I looked at were
- 22 definitely -- at least on the ones that were more
- 23 advanced in their consideration, had more flesh on the
- 24 bone than the one described here for OEW -- I'm sorry,
- 25 for 203. They were more thorough.

- 1 Q. And earlier you noted that part of the basis for
- 2 your opinion that 203 was not a good strategic fit for
- 3 Endo was that the words "Parkinson's disease" did not
- 4 appear in Endo's strategic documents that you reviewed.
- 5 Did you see the word "neurology" appear anywhere
- 6 in Endo's strategic documents that you reviewed?
- 7 A. I don't recall.
- 8 Q. How about the phrase "CNS"?
- 9 A. I don't recall.
- 10 Q. Do you have an understanding of what "CNS"
- 11 stands for?
- 12 A. Of course.
- 13 Q. Would you mind telling me?
- 14 A. Central nervous system.
- 15 Q. Thank you.
- 16 Would you consider Parkinson's disease
- 17 treatments to be generally within the category of
- 18 neurology and CNS treatments?
- 19 A. Yes.
- 20 Q. Okay. If you would turn to tab 3 of your
- 21 binder, please, and this is a 2008 Endo opportunity
- 22 evaluation worksheet which is listed in your materials
- 23 considered. It's branded only with a Bates number
- 24 because this has not been admitted into evidence, and it
- 25 does contain some Endo confidential information, so

- 1 please do not read it aloud and please confine your
- 2 answers to my questions.
- 3 Do you recall --
- 4 MR. BUTRYMOWICZ: Your Honor, excuse me. I have
- 5 to object. I don't see this document on the list of
- 6 Dr. Geltosky's materials considered, and I don't know
- 7 that there's otherwise a foundation for it.
- 8 JUDGE CHAPPELL: Take a moment and talk about
- 9 it.
- 10 (Counsel conferring.)
- 11 MS. FABISH: Just give me a moment to confirm
- 12 while I'm looking on this list.
- This is a fairly long list, and I don't know
- 14 that I have time to confirm for certain that it is not
- 15 on there, but I do think that it's properly within the
- 16 scope of cross examination. Dr. Geltosky has stated he
- 17 looked at several other opportunity evaluation
- 18 worksheets and compared the way that they approached
- 19 diligence and deals at Endo to the way that was done in
- 20 the opportunity evaluation worksheet at Endo. These
- 21 documents also speak to Endo's strategic goals.
- 22 MR. BUTRYMOWICZ: Your Honor, the list is long,
- 23 but it's in numerical order, and I -- comparing this
- 24 document's Bates number to where it would appear on the
- 25 list, it appears to be absent.

- 1 Additionally, I don't see that there's been any
- 2 foundation for this document as to what it is, whether
- 3 it's final. I don't see a date on it. I -- I don't
- 4 know that really there's any foundation for this.
- 5 JUDGE CHAPPELL: She's no longer saying that
- 6 it's on the list. She's saying it's within the scope of
- 7 fair cross. What's your response to that?
- 8 MR. BUTRYMOWICZ: Your Honor, I don't believe
- 9 it's within the scope of fair cross given that
- 10 Dr. Geltosky didn't testify about it, there's no
- 11 indication that he's reviewed it, and after looking at
- 12 the face of the document, it's not clear -- there is no
- 13 date, there's -- there appears to be some missing --
- 14 missing information. It's also not on JX 2. It is not
- 15 in evidence, and I don't know that there's a foundation
- 16 for it.
- MS. FABISH: And to be clear, Your Honor, I am
- 18 not attempting to offer it into evidence. I would
- 19 solely like to use it for the purposes of cross
- 20 examining Dr. Geltosky on his opinions regarding the
- 21 strategic business fit, which is addressed squarely in
- 22 this Endo document.
- JUDGE CHAPPELL: All right. Let's start again.
- 24 Rephrase your question with a proper foundation and see
- 25 if we get an objection.

- 1 BY MS. FABISH:
- Q. So, Dr. Geltosky, we established earlier that
- 3 you reviewed various opportunity evaluation worksheets
- 4 prepared at -- various Endo opportunity evaluation
- 5 worksheet documents in forming your opinions in this
- 6 matter, correct?
- 7 A. Well, they really didn't help me -- yes, it --
- 8 yes, they did, in my review of -- I was looking for
- 9 specific information in those OEWs. I wasn't really
- 10 digging for anything else in terms of qualifying -- I
- 11 was looking for whether they were doing sensitivity
- 12 analyses and market research on their other projects.
- 13 That's why I was looking at them.
- 14 Q. Okay. But you reviewed those documents in full,
- 15 correct?
- 16 A. I wouldn't say I read them in full. I was
- 17 searching for key words.
- 18 Q. Okay. Do you recall whether any of those
- 19 documents spoke to Endo's strategic business goals?
- 20 A. I wasn't -- that's not what I was looking for.
- 21 MS. FABISH: Your Honor, may I have a moment to
- 22 confer with counsel?
- JUDGE CHAPPELL: Go ahead.
- 24 (Counsel conferring.)
- 25 BY MS. FABISH:

- 1 Q. So if you could take a look at tab 3, you'll see
- 2 there is a section with the heading "Fit." Do you see
- 3 that?
- 4 MR. BUTRYMOWICZ: Your Honor, I have to object
- 5 again to the use of this document. I -- looking at it
- 6 further, it doesn't appear to be dated. There is no
- 7 indication that Endo entered this agreement. For
- 8 example, I -- I'm sensitive to counsel's representation
- 9 that this is -- that this is partially in camera, so I
- 10 won't read from the document, but there are indications
- 11 in it that Endo is still in a fairly early stage of
- 12 considering whether or not to go forward with this. I
- 13 just don't think that counsel has established really any
- 14 foundation for what this is or what it represents.
- 15 JUDGE CHAPPELL: The current question is, do you
- 16 see it? If you're objecting to that, it's overruled.
- 17 Go ahead.
- 18 BY MS. FABISH:
- 19 Q. Do you see where it says "Fit" in the second
- 20 paragraph?
- 21 A. Yes.
- 22 Q. And do you see that under that heading, there's
- 23 a reference to "CNS targeted product" in the second
- 24 line?
- 25 A. Yes.

- 1 Q. And you -- do you see that there is a reference
- 2 in the second-to-last line to the asset at issue
- 3 overlapping with neurology call points?
- 4 A. Yeah.
- 5 MR. BUTRYMOWICZ: Your Honor, I'm sorry, I have
- 6 to object again to this line of questioning. I don't
- 7 see how having Dr. Geltosky read from this document
- 8 that's not in evidence -- I'm not sure where counsel's
- 9 going with this, but it's hard to see how she's going
- 10 anywhere other than to try to ask questions about this
- 11 document that I think would be improper or to have him
- 12 read parts of it into evidence.
- MS. FABISH: Your Honor, if I may?
- 14 JUDGE CHAPPELL: I don't think we've heard the
- 15 question yet. Go ahead.
- MS. FABISH: Thank you.
- 17 BY MS. FABISH:
- 18 O. You testified earlier that you had not seen the
- 19 word "Parkinson's disease" or the word "CNS" in any Endo
- 20 documents --
- 21 A. No, that's not what I testified. I did not see
- 22 the word "neurology," and I don't remember whether I saw
- 23 the letters "CNS."
- Q. Okay. You can set that aside for now.
- Now, I do know that you included the

- 1 investigational hearing testimony of Dr. Robert Cobuzzi
- 2 in your materials considered list, correct?
- 3 A. Yes.
- 4 Q. Okay. Did you read -- I'd like you to turn, if
- 5 you would, to tab 10, which is the transcript of that
- 6 proceeding, and turn to page -- mini page 23, lines 19
- 7 to 22. In considering this transcript --
- 8 THE COURT: Wait until he says he's there.
- 9 THE WITNESS: I'm sorry. I see it.
- 10 BY MS. FABISH:
- 11 O. Do you see it?
- 12 A. Yes.
- 13 Q. In considering this transcript in forming your
- 14 opinions, did you consider the portion of his testimony
- 15 at page 23, starting at line 19, where he identifies
- 16 pain and neurology as two of the key areas of focus for
- 17 Endo's pharmaceutical products?
- 18 A. Yeah. I mean, at this time or at some point
- 19 they were selling a migraine drug, which is in the pain
- 20 franchise, and one of the rationales was that that was
- 21 their -- I believe their only pain product at the time,
- 22 and they were looking to add other neurology products,
- 23 and they used -- they were using terminology like
- 24 "adjacency," so Parkinson's is adjacent to pain and we
- 25 can use our same sales reps to detail both products.

- 1 The problem there is Frova would go off patent long
- 2 before 20 -- I'm sorry, 2003, would never see the light
- 3 of day, so that rationale was not appropriate.
- 4 Q. I'm sorry, I don't see any discussion of
- 5 adjacent fields or Frova on this page. I'll read you
- 6 the portion I'm referring to just to make sure that
- 7 we're clear.
- 8 On line 14:
- 9 "QUESTION: What was the corporate strategy when
- 10 you started in that position?
- 11 "ANSWER: Pharmaceutical products in general.
- 12 "QUESTION: That sounds very broad.
- 13 "ANSWER: Yes.
- 14 "QUESTION: Was there any focus on certain areas
- 15 of pharmaceutical products?
- 16 "ANSWER: Pain, neurology were the two key
- 17 areas."
- Did you consider this testimony, that pain and
- 19 neurology were two of the key areas of focus for
- 20 pharmaceutical products at Endo, in reaching your
- 21 opinions about the strategic fit of 203 with Endo's
- 22 business goals?
- 23 A. That didn't really -- well, I mean...
- Q. Okay. Now, when we spoke last month --
- JUDGE CHAPPELL: I don't think you got an

- 1 answer --
- 2 MS. FABISH: Oh, I thought he said no.
- JUDGE CHAPPELL: Did you answer that?
- 4 THE WITNESS: I would answer no.
- 5 MS. FABISH: Okay, thank you.
- 6 Thank you, Your Honor.
- 7 BY MS. FABISH:
- 8 Q. When we spoke last month about your opinions on
- 9 Endo, you mentioned that in the course of your work as a
- 10 consultant, you had approached Endo about investing in
- 11 two of your consulting clients' products. Do you recall
- 12 that?
- 13 A. Yes.
- 14 Q. Okay. And you told me that it was your opinion
- 15 that one of the assets you brought to Endo was -- and
- 16 I'm quoting -- "very strategic for Endo" and was in
- 17 Endo's "sweet spot." Do you recall that?
- 18 A. Yes.
- 19 Q. And did Endo ultimately decline to invest in
- 20 those products?
- 21 A. Ah, yes.
- 22 Q. So would it be fair to say, based on that
- 23 response, that you were incorrect about that asset being
- 24 very strategic for Endo or it being in Endo's sweet
- 25 spot?

- 1 A. Well, the area is very strategic. They wound up
- 2 buying a company called Auxilium with a more advanced
- 3 product. So it was strategic. It was just too early
- 4 for them.
- 5 O. So that's a no?
- 6 A. The question is? It is -- it is --
- 7 Q. Would you say --
- 8 A. -- they turned it down not because it was not
- 9 strategic. It, in fact, was strategic. That's not --
- 10 that's not the only criterion by which to execute an
- 11 agreement. They were very -- this was a testosterone
- 12 replacement product. This was in men's health, their
- 13 new area of focus, and they wound up buying a company
- 14 called Auxilium, which I believe had a marketed product.
- 15 So they jumped over what I had to offer, which was a
- 16 development compound.
- 17 Q. I see. But you initially thought they might be
- 18 interested in that compound that your client had
- 19 developed, correct?
- 20 A. Yes.
- Q. And it turns out they were not, correct?
- 22 A. They were not interested enough to execute an
- 23 agreement.
- Q. Okay, thank you.
- Now, I wanted to follow up on just -- this has

- 1 no relation to what we were just speaking about -- to
- 2 something that you said when you were speaking with
- 3 Complaint Counsel about just the general process for
- 4 diligence. You mentioned that one step in the process
- 5 of diligence is executing a confidentiality -- a CDA,
- 6 and you testified, I believe, that that's something that
- 7 you wouldn't take lightly. Do you recall that?
- 8 A. Yes.
- 9 Q. Do you recall when the CDA that the parties used
- 10 for the diligence at issue here was executed in this --
- 11 A. No, I don't.
- 12 O. I'd like to speak briefly about reasonable
- 13 commercial efforts. You don't have an opinion on
- 14 whether Impax exercised reasonable commercial efforts to
- 15 develop the subject product under the DCA, do you?
- 16 A. I do.
- 17 Q. You do have an opinion as to whether Impax
- 18 exercised --
- 19 A. Yes, as evidenced by the fact --
- 20 Q. Before you answer, sir -- and I apologize for
- 21 interrupting -- but do you recall when I asked you that
- 22 question at your deposition?
- 23 MR. BUTRYMOWICZ: Your Honor, I would like to
- 24 object. I think this is outside the scope of the direct
- 25 examination. I don't recall discussing whether Impax

- 1 used reasonable commercial efforts.
- MS. FABISH: Well, Your Honor, he did speak to
- 3 the efforts that Impax made to develop the product
- 4 after, and I wanted to clarify whether he was attempting
- 5 to offer an opinion which would be outside the scope of
- 6 his expert report regarding whether or not those efforts
- 7 met the reasonable commercial efforts standard. In
- 8 addition, he does discuss reasonable commercial efforts
- 9 generally in his report.
- JUDGE CHAPPELL: Are you saying you're
- 11 attempting to impeach his report?
- MS. FABISH: I'm not attempting to impeach his
- 13 report. I'm trying to clarify the scope of the opinions
- 14 that he is offering with respect to reasonable
- 15 commercial efforts.
- 16 JUDGE CHAPPELL: That's allowed. Overruled.
- 17 BY MS. FABISH:
- 18 Q. Do you have an opinion as to whether Impax
- 19 exercised reasonable commercial efforts to develop the
- 20 subject drug product under the DCA?
- 21 A. Today, I would say they -- I have an opinion.
- 22 They did not.
- 23 O. And are you offering an opinion in this matter
- 24 as to whether or not that's the case?
- 25 A. Yes.

- 1 Q. Can you point me to the portion of your report
- 2 that includes that opinion, sir?
- 3 A. I don't believe it's in there.
- 4 Q. It is not in your report?
- 5 A. Right.
- 6 MS. FABISH: Your Honor, I would like to move to
- 7 strike Dr. Geltosky's testimony on that subject as he
- 8 has acknowledged that it is not within the scope of his
- 9 report.
- 10 MR. BUTRYMOWICZ: Your Honor, Respondent's
- 11 counsel directly asked him about that, and I don't think
- 12 that's warranted.
- 13 JUDGE CHAPPELL: The rule here is that opinions
- 14 outside the reports are not allowed. If you're moving
- 15 to strike, it's granted.
- MS. FABISH: Thank you, Your Honor.
- 17 JUDGE CHAPPELL: Neither side can expound the
- 18 opinions -- can expand on the opinions that have been
- 19 submitted. One thing about these proceedings, the
- 20 experts' opinions are locked in. That's the way it
- 21 works.
- Go ahead.
- MS. FABISH: Thank you, Your Honor.
- 24 BY MS. FABISH:
- 25 Q. Dr. Geltosky, I'd like to speak briefly to

- 1 follow up on a few things about your background and
- 2 experience that you discussed with Complaint Counsel
- 3 earlier today.
- 4 You described how you began your career in
- 5 research and diagnostics and research and development
- 6 around 1980. Is that correct?
- A. Correct.
- 8 Q. And based on your CV, it appears to me that from
- 9 1980 to about 1994, you did not have any positions with
- 10 business development responsibilities. Is that correct?
- 11 A. Formally speaking, that's correct.
- 12 O. Okay. And you also noted earlier today that --
- 13 fast-forwarding quite a bit to your work now with JEG
- 14 Consulting, that your typical client at JEG is a small
- 15 biotech company. Do you recall that?
- 16 A. Yes.
- 17 Q. And you also testified that these companies are
- 18 net sellers in the potential collaborations that are the
- 19 subject of your consulting work, correct?
- 20 A. Correct.
- 21 Q. Okay. So working on behalf of those clients,
- 22 you were trying to get other companies to invest in a
- 23 product that the client had developed or was developing,
- 24 correct?
- 25 A. That's correct.

- 1 Q. And under those circumstances, the other company
- 2 was doing diligence on your client's asset, correct?
- 3 A. That's correct.
- 4 Q. Okay. And isn't it true that the bulk of the
- 5 experience that you have assessing a pharmaceutical
- 6 product for a potential investment on behalf of the
- 7 company potentially investing, so on behalf of a net
- 8 buyer, came from your time at Bristol-Myers Squibb and
- 9 SmithKline Beecham?
- 10 A. Yeah. The majority of the experience, yeah.
- 11 O. And both Bristol-Myers Squibb and SmithKline
- 12 Beecham were multimillion dollar companies when you
- 13 worked for them, correct?
- 14 A. Correct.
- 15 Q. And their R&D budgets would have also been in
- 16 the millions. Is that correct?
- 17 A. That's correct.
- 18 Q. So beyond your work on in-licensing deals at
- 19 Bristol-Myers Squibb and SmithKline Beecham, in terms of
- 20 assessing a pharmaceutical product for potential
- 21 investment, on behalf of a company potentially
- 22 investing, you also played this role while consulting on
- 23 two deals with clients of JEG, correct?
- 24 A. Yes.
- 25 Q. And you played that role while consulting on one

- 1 deal while working with an outfit called C14 Consulting,
- 2 correct?
- 3 A. Yeah. That's correct, yeah.
- 4 Q. And I understand you see yourself as playing a
- 5 similar role in reviewing the various grant applications
- 6 in connection with your role with CPRIT. Is that
- 7 correct?
- 8 A. That's correct.
- 9 Q. And that's all in terms of work assessing a
- 10 pharmaceutical product for potential investment on
- 11 behalf of the company potentially investing on behalf of
- 12 the net buyer, correct?
- 13 A. Yes.
- 14 Q. Okay. We've also spoken to varying extents
- 15 throughout the day about financial analyses, and you
- 16 testified that you had provided input into financial
- 17 valuations of potential pharmaceutical collaborations
- 18 over the course of your career, correct?
- 19 A. Correct.
- 20 Q. Okay. And this took the form of you providing
- 21 technical input to someone else who was preparing a
- 22 valuation analysis, correct?
- 23 A. Correct.
- Q. Okay. But you, yourself, never actually
- 25 performed such a valuation, correct?

- 1 A. Correct. It was always a team effort.
- 2 O. Okay. You view the diligence process at all
- 3 pharmaceutical companies as very, very similar. Is that
- 4 fair to say?
- 5 A. Yes.
- 6 Q. And you view your knowledge of this process as
- 7 one of the primary reasons clients hire you as a
- 8 consultant. Is that right?
- 9 A. I'm sorry? I'm having a hard time hearing you.
- 10 Q. No problem.
- 11 You view your knowledge of that process as one
- 12 of the primary reasons your clients hire you as a
- 13 consultant. Is that right?
- 14 A. Well, my knowledge of the industry in general,
- 15 the people on the other side, what they're looking for,
- 16 how to properly prepare a package to make it attractive
- 17 to a potential buyer, that's why they hire me.
- 18 Q. But how to prepare -- properly prepare a package
- 19 to make it attractive, that would include knowledge
- 20 about how that potential partner is diligencing a deal,
- 21 correct?
- 22 A. Well, they were all diligencing it the same way.
- 23 I knew what they were looking for. They were looking
- 24 for the same things I would look for if I were sitting
- 25 back at BristolMeyers. So that's why they hire me.

- 1 Q. Okay, that answered my question.
- 2 You've been -- how long have you been doing
- 3 consulting work for your own consulting firm, JEG
- 4 Consulting?
- 5 A. Golly, approximately ten years now.
- 6 Q. Okay. And during the course of those ten years,
- 7 how many potential deals have you been involved in?
- 8 A. Probably roughly a dozen or so.
- 9 Q. And in how many instances over those ten years
- 10 and in those dozen deals has your work for the client
- 11 resulted in an executed agreement?
- 12 A. Well, none. I was extremely close to getting
- 13 two of them done, and the companies decided they wanted
- 14 to be bought rather than to effect a business
- 15 development transaction. So I' teed everything up for
- 16 them, and they brought in bankers to effect a
- 17 merger/acquisition.
- 18 Q. Okay.
- 19 A. And I was involved, you know, as a consultant
- 20 with JSB, who we talked about before, and there we
- 21 concluded two transactions.
- 22 Q. So just to clarify, over the ten years that
- 23 you've been working with JEG Consulting, there have been
- 24 no executed deals as a result of your work.
- 25 A. Incorrect. Again, under the umbrella of JEG,

- 1 there was a company that we talked about before called
- 2 JSB for whom I consulted, and in that -- in that
- 3 two-year period that I was associated with them, we
- 4 executed two deals.
- 5 Q. Okay. So that two-year period that you were
- 6 associated with JSB, did that overlap with the ten years
- 7 that you were associated with JEG?
- 8 A. It was included in that time period, yes.
- 9 Q. So over the course of those ten years, your
- 10 consulting work has resulted in two completed deals?
- 11 A. That is correct.
- 12 Q. Okay.
- 13 A. And I have done work for other clients who wound
- 14 up doing fairly major transactions, but I wasn't
- 15 involved in them. I teed up a lot of the work for them
- 16 in terms of putting the packages together. They weren't
- 17 ready yet, and they wound up actually having some very
- 18 nice transactions and companies being bought.
- 19 Q. So I'm not sure I understand the relationship
- 20 between that to my question, so I will ask you my
- 21 question again, and I will ask you, to the extent
- 22 possible, to please just respond yes or no.
- 23 In the -- did the consulting work that you
- 24 performed while associated with JEG and JSB over the
- 25 past ten years result in two deals?

- 1 A. That's correct, yes.
- 2 Q. Thank you.
- 3 Just one last question. You spoke quite a bit
- 4 about Endo's diligence efforts -- due diligence that it
- 5 performed regarding the DCA and disagreed with various
- 6 aspects of the way that it approached that. Do you --
- 7 none of those criticisms apply to anything that Impax
- 8 did, correct?
- 9 A. That is correct.
- 10 MS. FABISH: I have no further questions. Thank
- 11 you, Your Honor. Thank you, Dr. Geltosky.
- 12 JUDGE CHAPPELL: Redirect?
- MR. BUTRYMOWICZ: Yes, Your Honor.
- 14 REDIRECT EXAMINATION
- BY MR. BUTRYMOWICZ:
- 16 Q. Good afternoon, Dr. Geltosky.
- 17 Respondent's counsel asked you how many deals
- 18 you had completed in your ten years as a pharmaceutical
- 19 consultant, and I believe that you responded that over a
- 20 ten-year period, out of about a dozen deals, two were
- 21 executed. Is that correct?
- 22 A. Ah, yeah. Those dozen were clients basically.
- 23 So, yes, and so each one we tried, and so there were two
- 24 that I was actively engaged in concluding.
- 25 Q. Based on your experience in the pharmaceutical

- 1 industry, is completing two out of 12 deals a low
- 2 success rate?
- 3 A. No, it's -- it's like drug discovery. I mean,
- 4 it's many -- I have no -- yeah, I think it's a
- 5 reasonable hit rate.
- 6 Q. Respondent's counsel also asked you about your
- 7 role as a consultant acting as a net seller. When you
- 8 were in that role, did you gain experience seeing how
- 9 the companies that you interacted with approached
- 10 development agreements?
- 11 A. Yes.
- 12 O. As a buyer?
- 13 A. Yes.
- 14 Q. Did you gain experience with how those companies
- 15 conducted diligence?
- 16 A. Yes.
- 17 Q. In that role, did you have experience with
- 18 companies that were similar in size to Endo
- 19 Pharmaceuticals?
- 20 A. Yes.
- Q. And in your experience as a buyer and a seller,
- 22 have all these companies approached development
- 23 agreements using the same general process that you've
- 24 outlined?
- 25 A. Yes.

- 1 Q. Respondent's counsel also asked if you relied on
- 2 documents from Endo that were provided by Complaint
- 3 Counsel. Did you have access to any internal Endo
- 4 business documents other than what Complaint Counsel
- 5 could provide to you?
- 6 A. No.
- 7 O. Were there any documents that you ever requested
- 8 that Complaint Counsel did not give you access to?
- 9 A. No.
- 10 Q. Complaint Counsel -- sorry, excuse me.
- 11 Respondent's counsel also asked you some
- 12 questions about data related to IPX-066, and I believe
- 13 you said that data relevant to IPX-066 could be useful
- 14 as a baseline to evaluate IPX-203. Is that correct?
- 15 A. That's correct.
- 16 Q. Why wouldn't this information be sufficient to
- 17 determine whether Endo should go forward with a
- 18 development deal for IPX-203?
- 19 A. It really wasn't relevant. I mean, that would
- 20 establish a baseline for which then 203 would have to
- 21 exceed in many ways to be a successful product, and
- 22 there was no way of knowing that at the time of the
- 23 agreement because there were no studies done on 203. So
- 24 it was just a benchmark, something to aspire to years
- 25 out when they finally got to the clinic.

- 1 Q. Respondent's counsel also asked you about the
- 2 information that was contained in the data room for
- 3 IPX-066. Do you recall that?
- 4 A. Yes.
- 5 Q. And you had reviewed that information as part of 6 preparing your report?
- 7 A. That's correct.
- 8 Q. Was there any information in that data room that
- 9 related specifically to IPX-203?
- 10 A. No.
- 11 Q. I'd like to ask you a few questions about
- 12 strategic fit, which Respondent's counsel asked about at
- 13 some length.
- I apologize. Let me go back. I have one more
- 15 question on the data room. Respondent's counsel asked
- 16 you if the data room contained intellectual property
- 17 information about IPX-066. Do you recall that?
- 18 A. Yes.
- 19 Q. And do you know from your experience in the
- 20 pharmaceutical industry whether pharmaceutical companies
- 21 do independent IP analyses before they enter development
- 22 agreements?
- 23 A. They do.
- Q. Did Endo do any independent analysis of the
- 25 intellectual property for IPX-203 before entering this

- 1 agreement?
- 2 A. Not that I could see from the documents
- 3 provided.
- 4 Q. All right. I'd now like to move on to strategic
- 5 fit. Respondent's counsel showed you a document from
- 6 Robert Cobuzzi, an executive at Endo, referencing, I
- 7 believe, "a good commercial fit." Do you recall that?
- 8 A. Yes.
- 9 Q. In preparing your report and coming to your
- 10 opinion, did you see any documents indicating that
- 11 IPX-203 was a good commercial fit that were dated before
- 12 Endo signed the co-development deal?
- 13 A. No.
- 14 Q. I would also like to ask you about some of the
- 15 testimony that Respondent's counsel reviewed with you.
- 16 Bear with me for a second as I try to find this.
- 17 If you could turn to tab 10 in the binder that
- 18 Respondent's counsel provided, which is the
- 19 investigational hearing transcript of Robert Cobuzzi,
- 20 and particularly to Minuscript page 23. Let me know
- 21 when you're there.
- 22 A. There.
- Q. Do you recall discussing this page with
- 24 Respondent's counsel?
- 25 A. Yes.

- 1 Q. And Respondent's counsel asked you about lines
- 2 19 through 22, which state:
- 3 "QUESTION: Was there any focus on certain areas
- 4 of pharmaceutical products?
- 5 "ANSWER: Pain, neurology were the two key
- 6 areas."
- 7 Do you see that?
- 8 A. Yes.
- 9 Q. I would like to direct your attention to a few
- 10 lines up, line 14, which says:
- 11 "QUESTION: What was the corporate strategy when
- 12 you started in that position?"
- 13 Do you see that?
- 14 A. Yes.
- 15 Q. When Mr. Cobuzzi was saying that pain and
- 16 neurology were two key areas, was he referring to when
- 17 he started in his position at Endo?
- 18 A. Yes.
- 19 Q. Do you know when Mr. Cobuzzi started at Endo?
- 20 A. No.
- 21 Q. If I could direct you to page 12 of this same
- 22 transcript, line 9. Let me know when you're there.
- 23 A. Yes.
- 24 Q. Line 9 says:
- 25 "QUESTION: How long have you been with Endo in

- 1 total?
- 2 "ANSWER: Since May 2nd, 2005."
- 3 Do you see that?
- 4 A. Yes.
- 5 Q. Does that provide any context for Mr. Cobuzzi's
- 6 testimony that pain and neurology were two key areas for
- 7 Endo?
- 8 A. No.
- 9 Q. Let me ask it differently.
- 10 Mr. Cobuzzi started at Endo in 2005.
- 11 A. Right.
- 12 Q. In his testimony on page 23, he states that when
- 13 he --
- 14 JUDGE CHAPPELL: Hold on a second.
- MR. BUTRYMOWICZ: Yes, Your Honor?
- 16 JUDGE CHAPPELL: Why are you going into another
- 17 witness' testimony in such detail on redirect?
- 18 MR. BUTRYMOWICZ: I apologize, Your Honor. I --
- 19 JUDGE CHAPPELL: Mr. Cobuzzi is not here.
- 20 MR. BUTRYMOWICZ: I understand, Your Honor. I
- 21 am trying to provide context for the questions that
- 22 Respondent's counsel asked about this set of testimony
- 23 to allow -- I don't believe Dr. Geltosky was given a
- 24 fair view of the context, and I'd like to get his
- 25 response to these questions with that understanding in

- 1 mind.
- JUDGE CHAPPELL: He's an expert witness. He's a
- 3 hired gun. He should be able to handle it. You go
- 4 ahead, but you don't have a whole lot of leeway left
- 5 here. You need to wrap this up and move to another
- 6 topic.
- 7 MR. BUTRYMOWICZ: All right, Your Honor. I'll
- 8 withdraw the question.
- 9 JUDGE CHAPPELL: If a man in his position can't
- 10 say when he thinks he's being trapped or needs more
- 11 context -- he's certainly capable of that, don't you
- 12 agree?
- 13 MR. BUTRYMOWICZ: I understand, Your Honor.
- 14 Yes, Your Honor.
- 15 BY MR. BUTRYMOWICZ:
- 16 Q. Let me just ask one final question on this
- 17 topic, putting aside that testimony. Did you see
- 18 anything in Mr. Cobuzzi's IH transcript that you
- 19 reviewed in preparing your report indicating whether
- 20 neurology was a key strategic area for Endo in 2010?
- 21 A. No.
- MR. BUTRYMOWICZ: Your Honor, I would like to
- 23 ask just a very few questions about the in camera
- 24 document that Respondent's counsel discussed at the
- 25 beginning of her cross examination, and so, regrettably,

- 1 I would ask that we go back into in camera session just
- 2 for a few minutes to do those questions.
- JUDGE CHAPPELL: At this time, we will go into
- 4 in camera session. I need to ask those who are not
- 5 subject to the protective order to vacate the courtroom.
- 6 Let me know if you see anyone in the courtroom
- 7 who should not be here.
- 8 MR. LOUGHLIN: Fine on our side, Your Honor.
- 9 MS. FABISH: No, Your Honor.
- 10 (Whereupon, the proceedings were continued in
- 11 in camera session.)
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(The following proceedings were held in
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- 1 (Public session.)
- JUDGE CHAPPELL: Thank you, you may stand down.
- 3 We are going to take a short break and then come
- 4 back for our last witness. We will reconvene at 4:50.
- 5 We're in recess.
- 6 (A brief recess was taken.)
- JUDGE CHAPPELL: Okay, we're back on the record.
- 8 Next witness.
- 9 MR. LOUGHLIN: Your Honor, Complaint Counsel
- 10 calls Bryan Reasons.
- JUDGE CHAPPELL: Okay, and we expect to wrap
- 12 this up no later than 6:00.
- 13 MR. LOUGHLIN: Thank you, Your Honor. My
- 14 colleague Jamie Towey will conduct the examination.
- 15 Whereupon--
- 16 BRYAN M. REASONS
- 17 a witness, called for examination, having been first
- 18 duly sworn, was examined and testified as follows:
- 19 JUDGE CHAPPELL: Go ahead.
- 20 MR. TOWEY: Good afternoon, Your Honor, and may
- 21 it please the Court. I am Jamie Towey on behalf of
- 22 Complaint Counsel.
- 23 DIRECT EXAMINATION
- 24 BY MR. TOWEY:
- 25 Q. Good afternoon, Mr. Reasons. How are you?

- 1 A. Good. How are you?
- Q. Good, thank you. We have not met before. My
- 3 name is Jamie Towey, and I will be asking you some
- 4 questions today.
- Why don't we start by having you please
- 6 introduce yourself by stating your full name.
- 7 A. Brian Marlon Reasons.
- 8 Q. And is there anything that might affect your
- 9 ability to give truthful, complete testimony here today?
- 10 A. No.
- 11 Q. Mr. Reasons, there should be a white binder next
- 12 to your chair there. We may refer to that throughout
- 13 the day. There's also a bottle of water if you need
- 14 that at any point.
- 15 A. Thank you.
- 16 Q. Mr. Reasons, who is your current employer?
- 17 A. Impax Laboratories.
- MR. TOWEY: Your Honor, pursuant to your order
- 19 dated October 18th, 2017, and Rule 4.1(d) of the
- 20 Commission rules, as a current employee of Impax,
- 21 Mr. Reasons is an adverse witness and subject to
- 22 examination by leading questions.
- JUDGE CHAPPELL: Okay.
- 24 BY MR. TOWEY:
- 25 Q. Mr. Reasons, you started at Impax in January of

- 1 2012, correct?
- 2 A. Yes.
- 3 Q. And prior to working at Impax, you had other
- 4 jobs in the pharmaceutical industry?
- 5 A. Yes.
- 6 Q. At Teva Pharmaceuticals?
- 7 A. Yes.
- 8 Q. And prior to that, at Cephalon?
- 9 A. Yes.
- 10 Q. In total, you have been employed in the
- 11 pharmaceutical industry for 12 to 13 years?
- 12 A. Yes.
- 13 Q. And about six of those years have involved
- 14 working at companies that produce generic products?
- 15 A. Yes.
- 16 Q. When you started at Impax, your position was
- 17 vice president of finance, correct?
- 18 A. Yes.
- 19 Q. You later became chief financial officer for
- 20 Impax, correct?
- 21 A. Yes.
- 22 Q. And that's your position today?
- 23 A. Yes.
- 24 Q. And you became chief financial officer around
- 25 December of 2012?

- 1 A. Yes.
- Q. As CFO, or chief financial officer, for Impax,
- 3 you report directly to the chief executive officer,
- 4 correct?
- 5 A. Yes.
- 6 Q. And as CFO, you have responsibility for
- 7 accounting functions?
- 8 A. Yes.
- 9 Q. And for SEC reporting?
- 10 A. Yes.
- 11 Q. For budgeting and forecasting?
- 12 A. Yes.
- 13 Q. For tax?
- 14 A. Yes.
- 15 Q. For investor relations?
- 16 A. Yes.
- Q. And for corporate communications?
- 18 A. Yes.
- 19 Q. As CFO at Impax, one of your responsibilities is
- 20 to communicate with the investment community, correct?
- 21 A. Yes.
- Q. And you participate in quarterly earnings
- 23 conference calls?
- 24 A. Yes.
- Q. And during those earnings conference calls, you

- 1 deliver prepared remarks?
- 2 A. Yes.
- Q. And you also answer questions from analysts?
- 4 A. Yes.
- 5 Q. And during those earnings conference calls, you
- 6 try to be accurate, correct?
- 7 A. Yes.
- 8 Q. And for those earnings conference calls, you try
- 9 to be knowledgeable about the topics you'll present?
- 10 A. Yes.
- 11 Q. Now I want to ask you some questions about the
- 12 Endo credit. You're familiar with that term, correct?
- 13 A. Yes.
- Q. And the Endo credit is a cash payment received
- 15 by Impax in 2013?
- 16 A. Yes.
- 17 Q. And the Endo credit was paid to Impax by Endo
- 18 Pharmaceuticals?
- 19 A. Yes.
- 20 Q. And the Endo credit was paid to Impax by Endo
- 21 because of provisions in a 2010 settlement agreement
- 22 relating to generic Opana ER?
- 23 A. Yes.
- Q. And the purpose of the Endo credit was to
- 25 protect Impax from Endo destroying the oxymorphone ER

- 1 market?
- 2 A. Yes.
- 3 Q. And oxymorphone ER is the generic name for Opana
- 4 ER?
- 5 A. Yes.
- 6 Q. Now, the Endo credit protected Impax by
- 7 requiring Endo to make payment to Impax if the
- 8 oxymorphone ER market declined before Impax could enter,
- 9 correct?
- 10 A. Yes.
- 11 Q. And the market for oxymorphone extended release
- 12 did decline before Impax could enter, correct?
- 13 A. Yes.
- Q. And that's why Impax received a payment from
- 15 Endo.
- 16 A. Yes.
- 17 Q. Within Impax, you were not responsible for
- 18 running the calculations of the Endo credit, were you?
- 19 A. I'm sorry. Could you repeat that?
- 20 O. Sure.
- 21 Within Impax, you were not responsible for
- 22 running the calculations of the Endo credit, correct?
- 23 A. I was not.
- Q. The people responsible for doing the calculation
- 25 of the Endo credit were in the Legal Department?

- 1 A. Correct.
- Q. But even though you weren't responsible for
- 3 running the calculation, you looked at the calculation
- 4 for mathematical accuracy, correct?
- 5 A. T did.
- 6 Q. And you were overall in charge of collecting the
- 7 Endo credit?
- 8 A. Yes.
- 9 Q. And you were overall in charge of accounting for
- 10 the Endo credit?
- 11 A. Yes.
- 12 Q. The payment that Impax received under the Endo
- 13 credit was more than \$100 million, correct?
- 14 A. Yes.
- 15 Q. In fact, the payment that Impax received under
- 16 the Endo credit was \$102,049,199.64?
- 17 A. I believe so.
- 18 O. For ease, when I'm referencing that, would you
- 19 be okay if I referenced that as 102 million?
- 20 A. Okay.
- 21 Q. Now, Impax received the \$102 million Endo credit
- 22 payment on April 18th, 2013, correct?
- 23 A. I believe so.
- 24 Q. And even before Impax received the Endo credit
- 25 payment, Impax was telling investors that it may receive

- 1 a \$110 million payment from Endo, correct?
- 2 A. Correct, based on Endo's public statements.
- 3 Q. And Impax told investors that because a
- 4 potential payment of \$110 million would be material to
- 5 the company?
- 6 A. Material to the cash flows, yes.
- 7 Q. When Impax received the Endo credit payment in
- 8 2013, it had an impact on Impax's net income.
- 9 A. It did.
- 10 Q. In fact, the payment had a substantial impact on
- 11 Impax's net income.
- 12 A. It did.
- 13 Q. The payment that Impax received increased its
- 14 2013 net income by about \$65 million, correct?
- 15 A. GAAP income, approximately, yes.
- 16 Q. And approximately 65 million is the \$102 million
- 17 Endo credit payment minus taxes?
- 18 A. Correct.
- 19 Q. That's how you got to 65 million?
- 20 A. Correct.
- 21 Q. As part of your job as CFO of Impax, you review
- 22 Impax's filings required by the Securities and Exchange
- 23 Commission, correct?
- 24 A. Yes.
- 25 Q. And you review them before they are filed?

- 1 A. Yes.
- Q. And you try to be accurate in the SEC filings.
- 3 A. Yes.
- 4 Q. You sign SEC filings when they're filed?
- 5 A. Yes.
- 6 Q. I'd like to ask you some questions about Impax's
- 7 10-K from the year in which it received the Endo credit
- 8 payment. If you could take the binder next to you and
- 9 turn to the tab marked CX 0425.
- 10 Your Honor, CX 0425 has been admitted into
- 11 evidence under JX 002 and is not subject to Your Honor's
- 12 in camera ruling.
- 13 I'd like to start, Mr. Reasons, on page
- 14 CX 0425-007, and, Ms. Wint, if I could ask you to pull
- 15 that page up on to the screen.
- 16 You're at that page?
- 17 A. Yes.
- 18 Q. Now, this is Impax's 10-K covering the fiscal
- 19 year ending December 31st, 2013?
- 20 A. Yes.
- 21 Q. And that was the year that Impax received the
- 22 Endo credit, correct?
- 23 A. Yes.
- Q. Okay. If we could turn now to page CX 0425-155,
- 25 and this is the signature block for the 10-K filing?

- 1 A. Yes.
- Q. And in the column of signatures, that's yours
- 3 below Larry Hsu's?
- 4 A. Yes.
- 5 Q. And did you review this document before filing
- 6 it?
- 7 A. Yes.
- 8 Q. And you believed it was accurate when it was
- 9 filed?
- 10 A. Yes.
- 11 Q. Okay. If I could have you turn to page
- 12 CX 0425-069. Are you there?
- 13 A. Yes.
- Q. Do you see the chart on that page?
- 15 A. Yes.
- Q. And the chart on this page shows Impax's net
- 17 income for 2012 and 2013.
- 18 A. Yes.
- 19 Q. And in 2013, the year that the Endo credit was
- 20 paid, Impax's net income was approximately \$101.3
- 21 million, correct?
- 22 A. Correct.
- Q. And looking at the chart, the highlighted area,
- 24 that's the 101,259?
- 25 A. Yes.

- 1 Q. And how can you tell if that's in millions?
- 2 A. At the front of the document, it says, "In
- 3 millions unless otherwise stated."
- 4 Q. Okay. And does the parenthetical at the top of
- 5 the chart also --
- 6 A. Yep.
- 7 O. -- tell you?
- 8 A. True.
- 9 O. Now, earlier you testified that net income from
- 10 the Endo credit was about \$65 million. Do I have that
- 11 right?
- 12 A. Yes.
- 13 Q. So to put that into perspective, the Endo credit
- 14 represented almost two-thirds of Impax's net income for
- 15 2013, correct?
- 16 A. Yes.
- 17 Q. And in the paragraph at the bottom of that page
- 18 that starts, "Net income for the year ended December 31,
- 19 2013" -- do you see that?
- 20 A. Yes.
- 21 Q. -- Impax said that the increase in net income
- 22 between 2012 and 2013 was primarily attributable to two
- 23 things, correct?
- 24 A. Correct.
- 25 Q. And the first of those things was the \$102

- 1 million Endo credit payment.
- 2 A. Correct.
- 3 Q. And the second of those was a \$48 million
- 4 payment that Impax received from another litigation
- 5 settlement, correct?
- 6 A. Correct.
- 7 Q. And both of those are pretax figures.
- 8 A. Correct.
- 9 Q. So according to the chart, Impax's net income in
- 10 2012 was about 55.9 million?
- 11 A. Correct.
- 12 O. So the \$65 million net income from the Endo
- 13 credit payment was about \$10 million more than all of
- 14 the net income from all of Impax in 2012.
- 15 A. Correct.
- 16 Q. You can put that document aside, and you can put
- 17 the binder aside as well for now.
- 18 I'm now going to ask some questions about
- 19 first-to-file exclusivity for generic Opana ER. You're
- 20 familiar with the term "first-to-file exclusivity"?
- 21 A. Yes.
- 22 Q. And first-to-file exclusivity applies to a
- 23 generic company if it's the first to file an ANDA under
- 24 certain circumstances?
- 25 A. Correct.

- 1 Q. And that first-to-file generic company has a
- 2 potential 180-day exclusivity period where no other ANDA
- 3 generics would be on the market?
- 4 A. Correct.
- 5 Q. So if Impax has first-to-file exclusivity for a
- 6 generic drug, typically other generic manufacturers
- 7 cannot come onto the market during that 180-day period,
- 8 right?
- 9 A. Correct.
- 10 Q. And being the only generic version of a branded
- 11 product has value for Impax.
- 12 A. Yes.
- 13 Q. For generic Opana ER, Impax had first-filer
- 14 exclusivity on five dosage strengths, correct?
- 15 A. I believe so.
- 16 Q. Do you know that that is a yes or you can't
- 17 recall the exact number?
- 18 JUDGE CHAPPELL: Do you think he's the best
- 19 person to ask about this? He's a CFO.
- 20 MR. TOWEY: And we are going to get into kind of
- 21 the financial significance of the exclusivity period,
- 22 Your Honor.
- JUDGE CHAPPELL: He said "I believe so," so go
- 24 ahead.
- MR. TOWEY: Yes, Your Honor.

- 1 BY MR. TOWEY:
- Q. I'll ask you a couple of questions now about
- 3 authorized generics. You're familiar with the term
- 4 "authorized generic"?
- 5 A. Yes.
- 6 Q. And that's sometimes abbreviated as "AG"?
- 7 A. Yes.
- 8 Q. And an authorized generic, or AG, is when the
- 9 brand manufacturer either launches their own version or
- 10 contracts another company to launch the generic version
- 11 of a branded product?
- 12 A. Yes.
- 13 Q. And while you've been at Impax, the company has
- 14 launched authorized generics of some of Impax's branded
- 15 products.
- 16 A. Can you say that again?
- 17 Q. While you have been at Impax, the company has
- 18 launched authorized generics of some of Impax's branded
- 19 products.
- 20 A. Ah, yes.
- 21 Q. And those were launched in response to generic
- 22 companies introducing generic versions of Impax's
- 23 branded products?
- 24 A. Yes.
- 25 Q. And authorized generics sold by Impax partially

- 1 offset sales of the branded product that were lost to
- 2 generic competition?
- 3 A. Yes.
- 4 Q. In fact, when Impax launched an authorized
- 5 generic, you discussed Impax's authorized generic with
- 6 analysts during earnings conference calls, correct?
- 7 A. Correct.
- 8 Q. Now, a branded manufacturer can compete with an
- 9 authorized generic during the 180-day exclusivity
- 10 period, correct?
- 11 A. Say that again.
- 12 O. Sure.
- 13 A branded manufacturer can sell its authorized
- 14 generic product during the 180-day exclusivity period of
- 15 an ANDA generic, the first-to-file ANDA generic,
- 16 correct?
- 17 A. I'm not -- I'm not sure if that's factual in
- 18 every circumstance.
- 19 Q. In your -- do you recall being deposed in this
- 20 matter in September of this year -- August of this year?
- 21 A. On this -- on this case or --
- 22 Q. Yes.
- 23 A. -- this specific question?
- Q. In this case.
- 25 A. Yes.

- 1 Q. And do you recall testifying that there's
- 2 nothing that prevents the brand name manufacturer from
- 3 releasing an authorized generic during the 180-day
- 4 period, typically?
- 5 A. I guess, yes.
- 6 Q. Do you agree with that statement?
- 7 A. If there's no other settlement, I do.
- 8 Q. And in general, an authorized generic is an
- 9 additional competitor in the generic marketplace,
- 10 correct?
- 11 A. Yes.
- 12 Q. Indeed, from Impax's perspective, there is no
- 13 difference between competing against an authorized
- 14 generic or a regular ANDA generic.
- 15 A. I agree.
- 16 Q. Except that an authorized generic can sell
- 17 during the exclusivity period.
- 18 A. Correct.
- 19 Q. And the effect of having an additional generic
- 20 competitor is usually a lower price, right?
- 21 A. A combination of either a lower price or lower
- 22 volume.
- Q. Are you ever aware of an additional generic
- 24 competitor not resulting in a lower price?
- 25 A. No.

- 1 Q. And generally speaking, in your experience,
- 2 adding a second generic will result in a price decrease
- 3 of about 30 to 35 percent?
- 4 A. Generally.
- 5 Q. And in addition to decreasing the price,
- 6 generally speaking, entry of a second generic product
- 7 will reduce the first generic's market share?
- 8 A. Generally.
- 9 Q. So rather than the first generic having 100
- 10 percent of generic sales, the two generic companies will
- 11 split those sales.
- 12 A. Usually.
- 13 Q. Now, you're aware that the 2010 settlement
- 14 agreement between Impax and Endo contained a clause
- 15 relating to Endo's sales of an authorized generic,
- 16 correct?
- 17 A. Yes.
- 18 O. And under that clause, Endo would not introduce
- 19 an authorized generic during Impax's 180-day exclusivity
- 20 period for certain strengths of Opana ER?
- 21 A. Yes.
- Q. For ease of reference, will you understand me if
- 23 I call this provision the no-AG agreement or the no-AG
- 24 provision?
- 25 A. Yes.

- 1 Q. And with the no-AG provision, there would be no
- 2 second generic of Opana ER during Impax's exclusivity
- 3 period, correct?
- 4 A. Correct.
- 5 Q. Having a no-AG provision, Impax could charge a
- 6 higher price for generic Opana ER than compared to a
- 7 marketplace that had two generics.
- 8 A. Repeat that, please.
- 9 O. Sure.
- 10 Having a no-AG provision, Impax could charge a
- 11 higher price for generic Opana ER than compared to a
- 12 marketplace that had two generics selling generic
- 13 products.
- 14 A. Ah, yes.
- 15 Q. And generally speaking, earlier you said that
- 16 that higher price is about 30 to 35 percent.
- 17 A. Yes.
- 18 Q. Now, the products that could reduce the price of
- 19 Impax's generic Opana ER were other generic versions of
- 20 Opana ER, correct?
- 21 A. Yes.
- Q. And it was other sellers of oxymorphone ER who
- 23 you identified to analysts in earnings conference calls
- 24 as the source of potential price erosion for Impax's
- 25 generic Opana ER, correct?

- 1 A. Correct.
- Q. I'd like you, again, to take the binder, and if
- 3 you could turn to a tab marked CX 2656.
- 4 Your Honor, while he's looking that up, I will
- 5 state that CX 2656 is included in JX 002 and has been
- 6 admitted into evidence, and this is a public document
- 7 and is not subject to your in camera ruling.
- 8 Are you there, Mr. Reasons?
- 9 A. Yes.
- 10 Q. And CX 2656 is a transcript from an earnings
- 11 conference call from May 2013, correct?
- 12 A. Yes.
- 13 Q. And this is a final version of the transcript?
- 14 A. It looks like it, yes.
- 15 Q. If I could have you turn to page CX 2656-007.
- 16 Ms. Wint, if you could publish that.
- I want to look at the middle of the page.
- 18 There's a line that says:
- 19 "Bryan Reasons: I guess I will clarify. You're
- 20 talking about oxymorphone -- generic oxymorphone."
- 21 Do you see that?
- 22 A. Yes.
- Q. And that was you speaking there?
- 24 A. Yes.
- 25 Q. And you're talking about generic Opana ER?

- 1 A. Yes.
- Q. In your next paragraph, after Jason Gerberry
- 3 says yes, you say in the middle of the paragraph:
- 4 "Obviously our exclusivity period ends in June
- 5 so, end of June, so we expect some competition then and
- 6 some price erosion."
- 7 Do you see that?
- 8 A. Yes, as it relates to our annual plan.
- 9 Q. And the exclusivity period you reference there
- 10 is the first-to-file exclusivity for generic Opana ER?
- 11 A. Yes.
- 12 Q. And when you say "we expect some competition,"
- 13 the competition was companies that would come out with
- 14 generic versions of Opana ER?
- 15 A. It's what we put in our plan, our budget.
- 16 Q. But those companies were other generic companies
- 17 selling generic versions of Opana ER.
- 18 A. As it relates to our plan, our annual plan, we
- 19 put in that we expect additional competition.
- 20 Q. And what I -- I understand this is part of your
- 21 plan. I'm just trying to understand who those -- that
- 22 competition was. So was that competition generic
- 23 companies selling generic versions of Opana ER?
- 24 A. Yes.
- 25 Q. And up until this point, rather than sharing the

- 1 generic marketplace, Impax had 100 percent share during
- 2 its first-to-file exclusivity period, correct?
- 3 A. Of the ER market, yes.
- 4 O. Yes.
- 5 A. Yes.
- 6 Q. And being the only generic version of this
- 7 branded product had value to Impax.
- 8 A. Yes.
- 9 Q. And in general, being the only generic version
- 10 is more valuable when sales of the branded product are
- 11 higher rather than lower, correct?
- 12 A. Yes.
- 13 Q. Thinking about this, I'd like to revisit the
- 14 no-AG agreement. A sharp decline in the sales of
- 15 branded Opana ER before Impax's generic launch would
- 16 decrease the value of the no-AG agreement, correct?
- 17 A. Yes.
- 18 O. And the value of the no-AG agreement would
- 19 decrease because the total market potential for generic
- 20 Opana ER was decreasing.
- 21 A. Yes.
- Q. And earlier we discussed, in the situation where
- 23 the market for Opana ER declined sharply before Impax's
- 24 launch, Impax might be eligible for payment of the Endo
- 25 credit, correct?

- 1 A. Correct.
- Q. So without a decline in the market for Opana ER,
- 3 the value of the no-AG provision would be higher, but if
- 4 the market did decline, then Impax could get a payment
- 5 under the Endo credit.
- 6 A. It could decline and no payment would be paid as 7 well.
- 8 Q. But it could -- it could decline and the Endo
- 9 credit payment would be required.
- 10 A. If it declined enough, yes, based on the
- 11 formula.
- 12 Q. I'd like to ask some questions now about how
- 13 Impax values a generic opportunity. You're familiar
- 14 with the term "automatic substitution"?
- 15 A. Yes.
- Q. And under automatic substitution, if a pharmacy
- 17 carries an Impax drug and the brand and the scrip is
- 18 written for the branded product, a pharmacist could
- 19 substitute the Impax AB rated generic for the brand.
- 20 A. Yes.
- 21 Q. So when Impax assesses the potential market
- 22 opportunity for a new generic drug, it looks at the size
- 23 of the corresponding brand's sales.
- 24 A. Correct.
- 25 Q. And it also looks to see if there's any existing

- 1 generics of that branded drug, correct?
- 2 A. Correct.
- Q. In fact, the best way to estimate the size of a
- 4 generic market opportunity is to look at the size of the
- 5 brand plus the existing generic products.
- 6 A. Yes.
- 7 Q. And that's the most accurate way to estimate the
- 8 potential market opportunity for a generic drug,
- 9 correct?
- 10 A. Could you repeat that?
- 11 Q. Sure.
- 12 You just said that it was the best way to
- 13 estimate the size of a generic market opportunity. It's
- 14 also the most accurate way to estimate the potential
- 15 market opportunity for a generic drug, correct?
- 16 A. Yes.
- 17 Q. Now I'd like to turn and ask some questions
- 18 about Impax's patent litigation expenses. As CFO,
- 19 you're responsible for the budgeting process at Impax.
- 20 A. Yes.
- 21 Q. And that includes budgeting for generic patent
- 22 litigation?
- 23 A. Yes.
- Q. And Impax reports its patent litigations in its
- 25 public filings, correct?

- 1 A. Correct.
- Q. And Impax reports its patent litigations as part
- 3 of its generic R&D expenses?
- 4 A. Correct.
- 5 Q. Patent litigations are -- let me start that
- 6 again.
- 7 Patent litigation expenses are largely comprised
- 8 of expenses from outside counsel, right?
- 9 A. Yes.
- 10 Q. And those are hourly fees from attorneys?
- 11 A. Yes.
- 12 O. And Impax might allocate a little bit for its
- 13 internal Legal Department as well, correct?
- 14 A. A little bit.
- Q. But it's just a little bit. Those are pretty
- 16 minor?
- 17 A. Um-hum, yes.
- 18 Q. Is that a yes?
- 19 A. Yes.
- Q. Now, the amount that Impax spends on a specific
- 21 patent litigation can vary based on a variety of
- 22 factors, correct?
- 23 A. Correct.
- Q. And one of those factors could be the length of
- 25 the litigation?

- 1 A. Correct.
- 2 O. And another of those factors would be whether
- 3 there's a settlement.
- 4 A. Correct.
- 5 Q. But for the budgeting process, you have to make
- 6 the best estimate you can for litigation expenses in
- 7 advance, correct?
- 8 A. Correct.
- 9 Q. And when you do that, the top end of the range
- 10 that you use for a generic patent litigation is about 3
- 11 to 4 million dollars?
- 12 A. Per -- per case?
- 13 Q. Per litigation, yes.
- 14 A. Yes.
- 15 Q. And the 3 to 4 million dollars, that's from the
- 16 start of litigation to the finish?
- 17 A. Yes.
- 18 Q. Now, for budgeting purposes, Impax has a single
- 19 line in its budget for patent litigation spending,
- 20 correct?
- 21 A. Yes.
- 22 Q. And for 2013, the -- 2013 was the first year
- 23 that you were the CFO and doing that process, correct?
- A. As the CFO, yes.
- Q. Yes. And do you recall that the total budgeted

- 1 patent litigation spending for 2013 was \$16.5 million?
- 2 A. That sounds right.
- 3 Q. Is that a yes or --
- 4 A. Yes. Yeah, yes.
- 5 Q. And the \$16.5 million was for all of Impax's
- 6 litigations in 2013.
- 7 A. Yes.
- 8 Q. And that was \$6 million higher than Impax had
- 9 originally planned for that year.
- 10 A. I -- I can't recall.
- 11 O. If I could -- if I showed you a budget
- 12 presentation that you made to the board of directors
- 13 with financial results from 2013, might that refresh
- 14 your recollection about the budgeted amount of patent
- 15 litigation expenses that year?
- 16 A. It would.
- 17 Q. All right. Then I'll ask you again, in the
- 18 binder, to turn to tab CX 3096.
- 19 Your Honor, this is in JX 002. It has been
- 20 admitted into evidence. It is covered, in part, by Your
- 21 Honor's in camera order, but I am using a redacted
- 22 version and will not be inquiring about any of the in
- 23 camera portions.
- JUDGE CHAPPELL: Okay.
- 25 BY MR. TOWEY:

- 1 Q. Mr. Reasons, if I could have you, when you get
- 2 there, to turn to page CX 3096-005. Ms. Wint, could I
- 3 get you to put that on the screen.
- 4 Are you on page 005?
- 5 A. Yes.
- 6 Q. Okay. At the very bottom of the chart, there
- 7 are three bullets. The bottom bullet says, "Patent Lit
- 8 (YTD) exceeded Plan by \$6 million, offset by delayed R&D
- 9 spending." Do you see that?
- 10 A. Yes.
- 11 Q. And does that refresh your recollection as to
- 12 whether patent litigations were \$6 million higher in
- 13 2013 than Impax originally planned?
- 14 A. Yes.
- 15 Q. And if I could have you put that document aside,
- 16 and I just asked if it refreshed your recollection, so
- 17 now I'll ask the original question again.
- So were Impax's patent litigation expenses \$6
- 19 million higher in 2013 than Impax originally planned?
- 20 A. Yes.
- Q. And even with that additional 6 million,
- 22 totaling 16.5 million in the budget for all of Impax's
- 23 litigation, that's a lot less than the \$102 million Endo
- 24 credit, correct?
- 25 A. Yes.

- 1 Q. And that's a lot less than the \$65 million in
- 2 net income for the Endo credit.
- 3 A. Yes.
- 4 MR. TOWEY: Your Honor, may I confer with
- 5 counsel?
- 6 JUDGE CHAPPELL: I couldn't understand you.
- 7 MR. TOWEY: May I confer with counsel, please?
- 8 JUDGE CHAPPELL: Yes, go ahead.
- 9 (Counsel conferring.)
- 10 MR. TOWEY: I have no more questions for direct
- 11 examination.
- 12 JUDGE CHAPPELL: Any cross?
- MR. ANTALICS: Yes, Your Honor.
- 14 JUDGE CHAPPELL: Go ahead.
- 15 CROSS EXAMINATION
- 16 BY MR. ANTALICS:
- Q. Mr. Reasons, you spoke about the settlement
- 18 agreement at some length with counsel. Do you recall
- 19 that?
- 20 A. Yes.
- Q. Okay. And you talked a little bit about the
- 22 Endo credit provision.
- 23 A. Yes.
- Q. Okay. Now, was there also a possibility under
- 25 the settlement agreement with Endo that a payment would

- 1 go in the other direction, from Impax to Endo?
- A. Yes. The settlement agreement was designed so
- 3 that if Endo was able to grow the market, Impax would
- 4 pay them a royalty.
- 5 Q. Okay. Well, between paying a royalty to Endo
- 6 and, on the other hand, receiving a payment from Endo
- 7 under the Endo credit, which is better from Impax's
- 8 financial perspective?
- 9 A. We would prefer to launch the generic into a
- 10 robust, large market and pay a royalty and have larger
- 11 ongoing revenue streams than have a one-time cash
- 12 payment that we would pull out of our GAAP results when
- 13 we report to the investors.
- 14 Q. In your experience, does the investment
- 15 community respond better to a one-time payment or a
- 16 stream of income into the future?
- 17 A. They tend to exclude the one-time payment and
- 18 are much more forward-looking and prefer forward-looking
- 19 revenues.
- 20 Q. Okay. Now, could Endo have moved the market to
- 21 a new formulation and at the same time have avoided
- 22 making a payment under the terms of the agreement?
- 23 A. Yes.
- 24 MR. TOWEY: Objection, Your Honor. Speculation.
- 25 THE WITNESS: Yes --

- 1 JUDGE CHAPPELL: Hold it. Hold it.
- THE WITNESS: Oh, sorry.
- JUDGE CHAPPELL: He objected to speculation.
- 4 What's your response?
- 5 MR. ANTALICS: Your Honor, Complaint Counsel
- 6 went on at length saying, well, if -- if sales went down
- 7 in the future, you know, would you receive a payment
- 8 under the Endo credit. I'm just trying to complete the
- 9 record here to get the witness' perspective on what
- 10 would result in a payment under the agreement and what
- 11 would not.
- 12 JUDGE CHAPPELL: Well, the way it's worded, I'm
- 13 not sure it's speculation. It's asking a direct
- 14 question. Could Endo have done this at that time?
- 15 MR. TOWEY: Right, but he has laid no foundation
- 16 that he knows what Endo could have or would have done.
- 17 JUDGE CHAPPELL: That's a different objection.
- 18 Are you objecting on foundation?
- 19 MR. TOWEY: Yes, Your Honor.
- JUDGE CHAPPELL: That's sustained. Speculation
- 21 is overruled. The answer will be disregarded.
- 22 MR. ANTALICS: May I rephrase it, Your Honor?
- JUDGE CHAPPELL: Yes.
- 24 BY MR. ANTALICS:
- 25 Q. Based on your reading of the agreement, is there

- 1 a way for -- was there a way for Endo to move the market
- 2 to a new formulation and at the same time avoid making a
- 3 payment under the agreement?
- 4 A. Yes.
- 5 MR. TOWEY: Objection, Your Honor. He's asking
- 6 for a legal conclusion. He's asking him to apply a
- 7 formula, and there is no foundation that he has applied
- 8 that formula.
- 9 JUDGE CHAPPELL: Do you want to rephrase and
- 10 make sure it's not legal?
- 11 BY MR. ANTALICS:
- 12 O. Having read the agreement, did you as a
- 13 businessman expect that a business strategy could have
- 14 been to move the market in a way that would avoid making
- 15 a payment under the Endo credit?
- 16 A. Yes. They could have moved the market down so
- 17 in the last quarter it would be down less than 50
- 18 percent and they would not have had to pay the credit.
- 19 Q. Okay. When was the first time that you heard a
- 20 payment would be due under the Endo credit provision?
- 21 A. Probably May of 2012 when Endo reported their
- 22 first quarter results and they publicly disclosed that
- 23 they accrued -- they had accrued for that credit.
- Q. Okay. Did you have an understanding as to what
- 25 triggered Endo's disclosure at that point?

- 1 JUDGE CHAPPELL: You mean does he know?
- 2 MR. ANTALICS: I think he'll testify to what
- 3 he's read.
- 4 JUDGE CHAPPELL: Let's find out what he knows
- 5 rather than what he understood.
- 6 BY MR. ANTALICS:
- 7 Q. Okay. Did you read anything -- any statements
- 8 from Endo describing the circumstances of the projected
- 9 payment to Impax?
- 10 A. Yes. Based on the -- the market -- the market
- 11 degradation at that time, they thought it was probable
- 12 that they would move the market enough to the
- 13 reformulated Opana that there would be a requirement of
- 14 the payment. I think they estimated it to be about 110
- 15 million, and that was fully disclosed, and they also
- 16 disclosed that it was partially a result of supply
- 17 issues with their Opana ER.
- 18 Q. Do you know what those supply issues were?
- 19 A. I believe Novartis was unable to supply them
- 20 product.
- 21 Q. Okay. You spoke earlier about the no-AG
- 22 provision. Do you recall that?
- 23 A. Yes.
- Q. And you talked about it with Complaint Counsel,
- 25 about it could have different values depending on the

- 1 size of the market, correct?
- A. Correct.
- Q. Okay. Well, if a branded company takes its
- 4 branded drug off the market before the generic can get
- 5 on the market, what would be the value of the no-AG
- 6 provision to the generic company?
- 7 A. It would not --
- 8 MR. TOWEY: Objection. Speculation.
- 9 THE WITNESS: If there was no --
- 10 JUDGE CHAPPELL: Hold it. Don't answer when
- 11 there's an objection pending.
- 12 THE WITNESS: Sorry.
- 13 JUDGE CHAPPELL: Are you going to respond to the
- 14 objection?
- 15 MR. ANTALICS: Could I rephrase it?
- 16 JUDGE CHAPPELL: Go ahead.
- 17 BY MR. ANTALICS:
- 18 Q. When you were reading the settlement agreement
- 19 and saw the no-AG provision there, as a businessperson,
- 20 were there circumstances in your mind under which the
- 21 no-AG provision would have no value?
- 22 A. Yes. If the -- if the branded market shrunk, it
- 23 would have less value. If the -- if the brand company
- 24 pulled the AB rated brand drug and moved it to another
- 25 brand, it would have no value.

- Q. And why would it have no value?
- 2 A. It -- it would not have a -- a substitutable
- 3 brand.
- 4 Q. Okay. You're referring to the automatic
- 5 substitution?
- 6 A. Yes. It wouldn't have an automatic
- 7 substitution.
- 8 Q. Okay. Now, you spoke at length about the
- 9 agreement on direct, correct, the settlement agreement?
- 10 A. Yes.
- 11 O. Okay. And you talked about the Endo credit
- 12 provision.
- 13 A. Yes.
- 14 Q. And you also talked about the no-AG provision
- 15 and when that might have value.
- 16 A. Yes.
- 17 Q. Okay. Okay. Within that settlement agreement,
- 18 there's another provision in there referring to a
- 19 co-development and license -- and -- a co-promotion and
- 20 development agreement. Do you recall that?
- 21 A. Yes, yes.
- 22 Q. Okay. What product did that co-promotion and
- 23 development agreement have to do with?
- 24 A. That's --
- MR. TOWEY: Objection, Your Honor. Beyond the

- 1 scope of direct.
- 2 MR. ANTALICS: Your Honor, Complaint Counsel
- 3 talked at length about the agreement, which, as you
- 4 know, throughout trial they have linked three payments
- 5 they claim from this agreement. They are claiming
- 6 there's a payment from the Endo credit, they're claiming
- 7 there was a payment from the no authorized generic, and
- 8 they're claiming that the co-promotion and development
- 9 agreement was inextricably linked and provided yet
- 10 another payment --
- 11 JUDGE CHAPPELL: All right, hold on. The
- 12 previous question said --
- MR. ANTALICS: I was getting into --
- 14 JUDGE CHAPPELL: -- he was asked about whether
- 15 he had talked about the agreement and a co-promotion and
- 16 development agreement.
- 17 MR. ANTALICS: Right.
- 18 JUDGE CHAPPELL: And is it your position that
- 19 you didn't ask about -- anything about what?
- 20 MR. TOWEY: The co-promotion and development
- 21 agreement.
- 22 JUDGE CHAPPELL: Based on the objection, you
- 23 need to lay a foundation.
- 24 MR. ANTALICS: Well, Your Honor, it's -- it's
- 25 within the document that -- that I think they -- I don't

- 1 recall if they showed it to them, but throughout the
- 2 trial, they've said this is part of the agreement --
- 3 JUDGE CHAPPELL: It doesn't matter what they've
- 4 said at trial. It doesn't matter what's in the
- 5 agreement. If he didn't ask about it, it's beyond the 6 scope.
- 7 Is this witness designated on your witness list?
- 8 MR. ANTALICS: Your Honor, we reserved the right
- 9 to designate witnesses that they called as --
- 10 JUDGE CHAPPELL: As I've said, you can attempt
- 11 to lay a foundation with this witness regarding what he
- 12 was asked on direct. If you can't do that, then move
- 13 along. I'm sustaining the objection.
- 14 MR. ANTALICS: Your Honor, my point, though, is
- 15 within the agreement that everybody's been talking about
- 16 and was talked about on --
- 17 JUDGE CHAPPELL: It doesn't matter what
- 18 everybody's talking about. What matters is what the
- 19 witness was asked on direct exam. That's the objection.
- MR. ANTALICS: Okay, okay.
- 21 JUDGE CHAPPELL: The objection is not this
- 22 hasn't come up in trial before. The objection is what
- 23 this witness was asked.
- 24 BY MR. ANTALICS:
- 25 Q. Were you asked about the settlement agreement --

- 1 A. Yes.
- 2 O. -- on direct examination?
- 3 A. Yes.
- 4 Q. Okay. And were you also asked about the no-AG
- 5 provision which is referenced in the settlement
- 6 agreement?
- 7 A. Yes.
- 8 Q. Okay. Is the co-promotion and development
- 9 agreement also referenced in the settlement agreement?
- 10 A. Yes.
- 11 MR. ANTALICS: Your Honor, I think it's relevant
- 12 if this witness --
- 13 JUDGE CHAPPELL: Relevance is not the issue.
- 14 The objection is beyond the scope.
- 15 MR. ANTALICS: I think it's within the scope --
- 16 JUDGE CHAPPELL: If you want to call this
- 17 witness on direct and he's on your list, we'll consider
- 18 that. If not, I haven't -- I didn't hear any questions
- 19 about the co-promotion agreement.
- 20 MR. ANTALICS: Well, Your Honor --
- 21 JUDGE CHAPPELL: And you didn't ask him that
- 22 question.
- 23 MR. ANTALICS: Let me try one more, Your Honor.
- 24 The Complaint Counsel have offered into evidence and
- 25 it's been accepted into evidence this witness'

- 1 deposition transcript in which, at length, they go into
- 2 the co-promotion and development agreement.
- Now, I suspect we will see at some point some
- 4 proposed findings of fact that relate to some of that
- 5 testimony. I'd like to give the witness an opportunity
- 6 to explain what he knows in a little more detail about
- 7 that agreement.
- 8 MR. TOWEY: And, Your Honor, they did not call
- 9 this witness, and they did not list this as a topic that
- 10 this witness would be talking about.
- 11 JUDGE CHAPPELL: You didn't respond to what he
- 12 just said. Do you plan on offering any deposition
- 13 testimony from the deposition of this witness?
- 14 MR. TOWEY: Any deposition testimony? At this
- 15 point, we don't know what we're going to offer.
- 16 JUDGE CHAPPELL: The objection's overruled. Go
- 17 ahead. That's why he's here. You can question him
- 18 about the deposition.
- 19 MR. ANTALICS: Okay.
- 20 JUDGE CHAPPELL: If they stood there and told me
- 21 they're not offering any excerpts whatsoever, I'm
- 22 cutting you off, but he didn't do that, so you go ahead.
- 23 MR. ANTALICS: Thank you, Your Honor. Okay.
- JUDGE CHAPPELL: It doesn't make sense to let
- 25 his deposition come in and he not be asked about topics

- 1 in the deposition. Since you didn't exclude that
- 2 possibility, you're overruled.
- 3 BY MR. ANTALICS:
- 4 Q. Mr. Reasons, during your deposition, did you
- 5 speak about the drug Rytary?
- 6 A. I did.
- 7 Q. And did you also speak in your deposition about
- 8 the development drug 203?
- 9 A. Yes, I did.
- 10 Q. Okay. Could you explain for the Court first,
- 11 what is Rytary?
- 12 A. Rytary is an extended-release carbidopa-levodopa
- 13 for the treatment of symptoms of Parkinson's.
- 14 Q. Okay. Can you describe generally what 203 is?
- 15 A. It's our next generation in which it's a
- 16 carbidopa-levodopa-based product that hopefully improves
- 17 the treatment of those symptoms and also has favorable
- 18 dosing over Rytary.
- 19 Q. Now, during the course of the development of
- 20 203, were there delays in that development?
- 21 A. There were.
- 22 Q. Okay. And what was the cause of those delays?
- 23 MR. TOWEY: Your Honor, I would object until
- 24 Mr. Antalics can point out where in his deposition this
- 25 is discussed, if the deposition is the basis for this

- 1 line of questioning.
- JUDGE CHAPPELL: Or lay a foundation that it's
- 3 within the deposition.
- 4 BY MR. ANTALICS:
- 5 Q. Okay. Do you recall speaking about delays in
- 6 the development of 203 which resulted in you not
- 7 receiving milestone payments?
- 8 A. I did.
- 9 MR. TOWEY: Objection. Is this from the
- 10 deposition or earlier testimony?
- 11 MR. ANTALICS: From the deposition.
- 12 JUDGE CHAPPELL: Restate the question.
- 13 BY MR. ANTALICS:
- 14 Q. Do you recall speaking about not receiving
- 15 milestone payments because of delays in the development
- 16 of 203 during the course of your deposition?
- 17 A. I do.
- 18 O. Okay. Now, what caused the delay in the
- 19 development of 203?
- 20 A. Well, 203 was the next generation of Rytary. It
- 21 was several years behind Rytary in the R&D cycle. When
- 22 Rytary was delayed, resources were put to focus on the
- 23 approval of Rytary so that we could get that to market,
- 24 grow that -- grow that commercially, and it would also
- 25 be beneficial to -- when we launched the next generation

- 1 of 203, to have a robust Rytary market.
- We felt it would also, to get through the Rytary
- 3 and get that approved, it would help from a regulatory
- 4 perspective in getting IPX-203 approved as well.
- 5 Q. Okay. Where is 203 today in terms of its
- 6 development?
- 7 A. 203, we've completed -- we've now completed
- 8 Phase II-A and II-B, are finishing our final review of
- 9 that, and we expect to start Phase III at the beginning
- 10 of 2018. It's our lead compound on the brand side of
- 11 our R&D programs. It's really our strategy to continue
- 12 to grow and extend the duration of our Parkinson's
- 13 franchise.
- Q. Based on your experience, are delays in
- 15 development of a new drug unusual?
- 16 A. They are very common.
- Q. Okay. And does it, from time to time, happen
- 18 that a new product development effort is unsuccessful?
- 19 A. It's very common.
- 20 Q. Okay. How many deals have you been involved in?
- 21 A. Over my career --
- MR. TOWEY: Objection, Your Honor.
- 23 THE WITNESS: -- hundreds --
- JUDGE CHAPPELL: Hold it. When someone objects,
- 25 you need to hold your answer.

- 1 THE WITNESS: Sorry.
- MR. TOWEY: It's beyond the scope. I don't know
- 3 of anywhere in the deposition where this was covered,
- 4 Your Honor.
- 5 MR. ANTALICS: Number one, his time frame at
- 6 Cephalon was covered. We're talking about and laying a
- 7 foundation for why he can speak about the development
- 8 progress and how that relates to other drugs. His
- 9 experience is certainly a factor in developing that
- 10 foundation, I think.
- 11 MR. TOWEY: Your Honor, I don't know of anywhere
- 12 in the deposition that he said anything about his
- 13 experience with drug development. He certainly wasn't
- 14 noticed for this topic by Respondent.
- 15 MR. ANTALICS: Your Honor, it's foundational,
- 16 his experience.
- 17 JUDGE CHAPPELL: Regarding what? Regarding
- 18 something on direct?
- MR. ANTALICS: As to why -- yes, as to issues
- 20 that he's -- he was -- that he's talked about during his
- 21 deposition, such as the delay, such as the \$10 million
- 22 payment, such as milestones, things like that.
- 23 JUDGE CHAPPELL: Are these questions in his
- 24 deposition?
- 25 MR. ANTALICS: Yes

- 1 JUDGE CHAPPELL: Well, you can offer those
- 2 excerpts.
- 3 MR. ANTALICS: Well, I'd like to hear -- to have
- 4 the -- I have maybe five or ten minutes on this, Your
- 5 Honor. I'd like the Court to hear -- you know, with the
- 6 benefit of the witness on the stand, if you have
- 7 questions or --
- 8 JUDGE CHAPPELL: So you're asking a foundational
- 9 question regarding a topic that was covered in the
- 10 deposition?
- 11 MR. ANTALICS: Right.
- 12 JUDGE CHAPPELL: I'll allow it for now.
- 13 Overruled.
- 14 THE WITNESS: Could you repeat the question?
- 15 BY MR. ANTALICS:
- 16 Q. Approximately how many deals were you involved
- 17 in in your experience?
- 18 A. In my career, a hundred.
- 19 Q. Okay. What kinds of deals were you involved in?
- 20 A. I mean, they would -- they would vary from major
- 21 M&A to in-licensing to co-developments to options to
- 22 license, options to co-develop, you know, a full gamut
- 23 of structures.
- Q. Is a \$10 million up-front payment unusual in a
- 25 co-development agreement?

- 1 A. It's quite --
- 2 MR. TOWEY: Objection, Your Honor. This is
- 3 nowhere in the deposition. He seems to be responding to
- 4 the prior witness and not to anything that I asked or
- 5 anything in the deposition.
- 6 JUDGE CHAPPELL: I haven't heard anything about
- 7 the up-front payment.
- 8 MR. ANTALICS: The up-front payment -- the \$10
- 9 million up-front payment certainly was discussed in the
- 10 deposition.
- 11 MR. TOWEY: Where was it discussed?
- MR. ANTALICS: On page 83.
- "QUESTION: Were you aware that Impax got an
- 14 up-front payment as part of the co-promotion agreement?
- 15 "ANSWER: Yes.
- 16 "QUESTION: Do you know how much that up-front
- 17 payment was?
- 18 "ANSWER: I believe it was 10 million."
- 19 And it goes on.
- MR. TOWEY: And, Your Honor, I see nothing here
- 21 that talks about comparisons to other deals or
- 22 Mr. Reasons' experience dealing with co-promotion and
- 23 development agreements.
- 24 JUDGE CHAPPELL: I think this one's getting a
- 25 little too far afield. I'm sustaining that. You can

- 1 move on.
- 2 MR. ANTALICS: I'm sorry, Your Honor?
- JUDGE CHAPPELL: You're getting a little too far
- 4 afield. I'm sustaining the objection. Move on.
- 5 BY MR. ANTALICS:
- 6 Q. With respect now to --
- 7 Your Honor, may I ask a separate question
- 8 relating to that \$10 million payment and -- that was --
- 9 should I just put forward the question and --
- 10 JUDGE CHAPPELL: Anything you ask, you need to
- 11 connect it to the deposition or the direct with the
- 12 witness, which you haven't been doing, because we have
- 13 got a foundation objection --
- MR. ANTALICS: Okay, all right.
- 15 JUDGE CHAPPELL: -- and a scope objection, both.
- 16 MR. ANTALICS: May I ask, Your Honor -- the
- 17 witness how the company accounted for the \$10 million
- 18 payment?
- 19 MR. TOWEY: It was not addressed on direct
- 20 examination, but I believe there is something in the
- 21 deposition on it.
- JUDGE CHAPPELL: Go ahead.
- BY MR. ANTALICS:
- Q. How did Impax account for that \$10 million
- 25 payment?

- 1 A. When we received it, we deferred it, and we
- 2 recognized it based on R&D work that was then
- 3 accomplished going forward.
- 4 Q. So can you explain a little more what you mean
- 5 by that? Did you recognize just a portion of it?
- 6 A. So we -- we -- when we received it, we
- 7 recognized zero, and as we did R&D work, we began to
- 8 recognize a portion of it over time, as it was earned,
- 9 because we -- it was related to R&D -- future R&D work.
- 10 Q. Okay. And are there any accounting rules or
- 11 standards that factored into that decision?
- 12 A. Yeah. There's a lot. It's -- there's lots of
- 13 standards around both revenue recognition and R&D
- 14 milestone accounting, and that's -- you know, we --
- 15 we -- we issue our financial statements in accordance
- 16 with GAAP and follow that.
- 17 Q. Okay. And are they filed with the SEC?
- 18 A. They are reviewed quarterly by our independent
- 19 accountants, audited annually, and signed off by not
- 20 only the accountants but the CEO and myself.
- 21 Q. Thank you.
- Your Honor, I have nothing further.
- JUDGE CHAPPELL: Redirect?
- MR. TOWEY: Yes, Your Honor.
- 25 May I have one moment?

- 1 JUDGE CHAPPELL: Go ahead.
- 2 (Counsel conferring.)
- 3 MR. TOWEY: I won't have too many questions,
- 4 Your Honor.
- 5 REDIRECT EXAMINATION
- 6 BY MR. TOWEY:
- 7 O. Is the current version of IPX-203 the product
- 8 that was covered by the confidentiality and disclosure
- 9 agreement that Impax signed with Endo?
- 10 A. I'm not sure.
- 11 Q. And is it the product of the co-promotion and
- 12 development agreement?
- 13 A. I'm not sure.
- Q. And you were just discussing with Mr. Antalics
- 15 when the \$10 million payment was recognized. Is that --
- 16 do you recall that?
- 17 A. Correct.
- 18 O. And when was the \$10 million finally recognized?
- 19 A. It was recognized over time as it was earned,
- 20 and then the remainder was recognized when Endo exited
- 21 the agreement.
- 22 Q. So when Endo exited the agreement, Impax had not
- 23 yet spent \$10 million on IPX-203?
- A. We had not fully recognized the milestone
- 25 payment, which is based on work accomplished, not spent.

- Q. So by the time that Endo exited the agreement,
- 2 Impax had not accomplished \$10 million worth of work
- 3 yet?
- 4 A. We had not fully recognized the \$10 million
- 5 milestone.
- 6 Q. Right. What I'm asking is, I'm trying to
- 7 understand what that means. Does that mean that Impax
- 8 had not done \$10 million worth of work by the time that
- 9 Endo exited the agreement?
- 10 A. No, it doesn't.
- 11 Q. How much work had Impax done?
- 12 A. We had -- I -- I'd have to go back and look at
- 13 how much exactly we'd spent, but I -- I don't recall off
- 14 the top of my head.
- 15 Q. But it had not recognized all \$10 million of
- 16 that up-front payment by the time you --
- 17 A. We had not recognized all 10 million of that
- 18 up-front payment, correct.
- 19 Q. Now, I want to ask some questions --
- 20 Mr. Antalics asked you some questions about whether Endo
- 21 could have timed the Endo credit such that it might have
- 22 been zero. Do you recall that?
- 23 A. Say it again. I'm sorry.
- Q. Mr. Antalics asked you some questions about
- 25 whether Endo could have timed the Endo credit such that

- 1 there may have been a zero payment under the Endo
- 2 credit.
- 3 A. Yes.
- 4 Q. And you don't know, at the time of settlement,
- 5 how long Endo thought it would take to convert original
- 6 Opana ER to a reformulated Opana ER, do you?
- 7 A. At the time of settlement? I didn't work at
- 8 Impax.
- 9 Q. So you don't know.
- 10 A. Right.
- 11 Q. And, in fact, at any point in time, you don't
- 12 know how long Endo thought it would take to convert from
- 13 original Opana ER to reformulated Opana ER, correct?
- 14 A. Correct.
- 15 Q. And you don't know, under any plan, how much
- 16 would be remaining in the distribution channels of
- 17 original Opana ER when Impax launched its generic?
- 18 A. Can you repeat that?
- 19 Q. Sure.
- 20 You don't know, under any Endo plan, how long --
- 21 how much would be remaining of generic Opana ER in the
- 22 distribution channels when Impax launched its generic.
- 23 A. I -- I did not know.
- Q. And you don't know, under any Endo plan, how
- 25 much would be remaining in the retail channels.

- A. I did not know.
- Q. And you do not know, under any Endo plan, what
- 3 percentage of patients would stay with Impax's generic
- 4 instead of converting to the reformulated product, if
- 5 there was anything left in the distribution and retail
- 6 channels, do you?
- 7 A. Ah, no.
- 8 Q. So, essentially, your testimony is speculation
- 9 based on no knowledge of Endo's plans.
- 10 A. No.
- 11 Q. Your testimony is not -- you do know about
- 12 Endo's plans?
- 13 A. Which -- which comments are you talking about?
- Q. So I just asked you a bunch of questions about
- 15 did you know Endo's plans, and you said no to each of
- 16 those questions --
- JUDGE CHAPPELL: Why don't you narrow that
- 18 question, because that was -- "your testimony is
- 19 speculation," that could include everything he's said.
- 20 You need to narrow this.
- MR. TOWEY: Thank you, Your Honor.
- 22 BY MR. TOWEY:
- 23 O. So your testimony about whether Endo could have
- 24 timed the Endo credit to equal zero is speculation about
- 25 what Endo thought it could do.

- 1 A. No. My testimony said that it could be timed.
- Q. But you don't know if Endo thought that.
- 3 A. I don't know what Endo thought.
- 4 Q. And you have not seen any Endo plans that would
- 5 allow you to conclude what Endo would do or could do.
- 6 A. I -- I never said that.
- 7 Q. So the answer is, no, you don't have any of that
- 8 information?
- 9 A. No, no.
- 10 Q. You -- also under examination by Mr. Antalics,
- 11 you answered that Impax would prefer to sell into a
- 12 robust market and have a stream of revenues rather than
- 13 a one-time payment, correct?
- 14 A. Correct.
- 0. And it's better to sell into that robust market
- 16 with only one generic rather than face the possibility
- 17 of two generics, correct?
- 18 A. Correct.
- 19 Q. But Impax knew that it wouldn't face another
- 20 generic because it had the no-AG agreement with Endo
- 21 under the settlement agreement, correct?
- 22 A. Repeat the question, please.
- 23 O. So Impax knew that it would not face another
- 24 generic in this -- if there was a robust market because
- 25 it had the no-AG agreement with Endo from the 2010

- 1 settlement agreement.
- 2 A. No. Generic competition would eventually come.
- 3 Q. But for the exclusivity period --
- 4 A. Oh, okay, you didn't say that. Repeat the
- 5 question, please.
- 6 Q. Sure.
- 7 If Impax were launching into a robust market
- 8 with first-to-file exclusivity, it would know, because
- 9 of the no-AG agreement, that it would not be facing any
- 10 generic competition.
- 11 MR. ANTALICS: Objection, Your Honor. We're
- 12 speculating at this point now.
- 13 JUDGE CHAPPELL: I think I recall him saying he
- 14 wasn't up on this exclusivity period, so I'm going to
- 15 sustain that without a foundation.
- 16 BY MR. TOWEY:
- 17 Q. Mr. Reasons, you said it's better to sell into a
- 18 robust market as the only generic, correct?
- 19 A. Yes.
- 20 Q. And the no-AG provision precluded Endo during
- 21 Impax's first-to-file exclusivity period from selling an
- 22 authorized generic, correct?
- 23 A. Yes.
- MR. TOWEY: May I confer with counsel, Your
- 25 Honor?

- 1 JUDGE CHAPPELL: Go ahead.
- 2 (Counsel conferring.)
- 3 BY MR. TOWEY:
- 4 Q. You also testified that there was a possibility
- 5 that Impax would pay a royalty under the settlement
- 6 agreement.
- 7 A. That's correct.
- 8 Q. And Impax would only pay that royalty if branded
- 9 Opana ER sales increased by certain thresholds prior to
- 10 Impax's launch, correct?
- 11 A. Correct.
- 12 Q. And in that circumstance, Impax would get value
- 13 from the no-AG provision even if it was paying the
- 14 royalty, correct?
- MR. ANTALICS: Objection. I think we're
- 16 speculating again.
- 17 JUDGE CHAPPELL: He objected to speculation.
- MR. TOWEY: I'm just asking for the logical
- 19 conclusion of what he was talking about with the
- 20 royalty.
- 21 JUDGE CHAPPELL: But a logical conclusion can
- 22 still be speculation. Unless you have something else, I
- 23 am going to sustain it.
- MR. TOWEY: I'll ask it a different way, then.
- 25 JUDGE CHAPPELL: All right.

- 1 BY MR. TOWEY:
- Q. If the market for Opana ER grew, the potential
- 3 for generic sales would increase as well, correct?
- 4 MR. ANTALICS: Objection, Your Honor.
- 5 Speculation.
- 6 MR. TOWEY: Your Honor --
- 7 MR. ANTALICS: It starts with "if." I think
- 8 we're automatically into speculation, Your Honor.
- 9 MR. TOWEY: Your Honor, earlier the witness
- 10 testified that Impax would rather sell into a larger
- 11 market than not. This is just --
- 12 JUDGE CHAPPELL: I am going to allow this, but
- 13 you need to wrap this up.
- 14 MR. TOWEY: Okay.
- 15 JUDGE CHAPPELL: Overruled.
- 16 BY MR. TOWEY:
- 17 Q. So let me ask the question again.
- 18 If the market for Opana ER grew, the potential
- 19 for generic sales would increase as well.
- 20 A. Yes.
- 21 Q. And in that larger market, there would be no
- 22 second generic competitor during Impax's first-to-file
- 23 exclusivity period, correct?
- 24 A. Correct.
- 25 Q. And that would allow Impax to charge a higher

- 1 price, correct?
- MR. ANTALICS: Objection, Your Honor. We're
- 3 speculating, if this happens and this happens, then this
- 4 would allow something else. It's speculation on
- 5 speculation.
- 6 MR. TOWEY: He's --
- JUDGE CHAPPELL: I haven't heard him say
- 8 anything about pricing.
- 9 MR. TOWEY: He talked about if there was a
- 10 one-generic market versus a two-generic market, it would
- 11 have a 30 to 35 percent price difference.
- 12 JUDGE CHAPPELL: The way you phrased the
- 13 question, even if he answers it, it's not going to do
- 14 you any good. Sustained.
- 15 BY MR. TOWEY:
- 16 Q. In a one-generic marketplace, Impax would have
- 17 100 percent of generic Opana ER sales, correct?
- 18 A. Correct.
- 19 Q. And if Impax faced competition from an
- 20 authorized generic, there would not be any -- Impax
- 21 would not have 100 percent --
- 22 MR. ANTALICS: Objection. We're, again --
- 23 JUDGE CHAPPELL: I'm allowing this one, but
- 24 that's it. Overruled. Answer the question, move on, or
- 25 sit down. We have beat this to death.

- 1 THE WITNESS: Can you say it one more time?
- 2 Sorry.
- 3 BY MR. TOWEY:
- 4 Q. Sure.
- 5 If Impax faced competition from an authorized
- 6 generic, then Impax would not have 100 percent of
- 7 generic Opana ER sales, correct?
- 8 A. Probably.
- 9 Q. Is there any marketplace which you, in your
- 10 experience, have faced where there are two generics and
- 11 one of them has 100 percent market share of the generic
- 12 product?
- 13 A. No.
- MR. TOWEY: I have no more questions, Your
- 15 Honor.
- 16 JUDGE CHAPPELL: Anything else?
- 17 MR. ANTALICS: Nothing, Your Honor.
- 18 JUDGE CHAPPELL: Thank you. You may stand down.
- We will reconvene Thursday, 9:45 a.m. We're in
- 20 recess.
- 21 (Whereupon, at 5:57 p.m., trial was adjourned.)
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Τ	CERTIFICATE OF REPORTER
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3	I, Susanne Bergling, do hereby certify that the
4	foregoing proceedings were recorded by me via stenotype
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